IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,	)	
Plaintiff,	)	C.A. No. 06-663-SLR
v.	)	**REDACTED - PUBLIC VERSION**
CORDIS CORPORATION,	)	
Defendant.	)	

OPENING BRIEF IN SUPPORT OF CORDIS CORPORATION'S MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(1) OR, IN THE ALTERNATIVE, TO DISMISS OR STAY THIS ACTION PENDING RESOLUTION OF THE CO-PENDING ACTION IN THE DELAWARE COURT OF CHANCERY

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Dated: November 16, 2006

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I. INTRODUCTION

This pretextual lawsuit was brought by Wyeth against Cordis Corporation ("Cordis") as a tactical ploy to gain leverage in an unrelated business dispute.

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Cordis used the rapamycin provided by Wyeth to develop the Cypher stent, the first drug eluting stent approved by the FDA in the United States.

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In reality, this suit is a bargaining chip created by Wyeth for use in a dispute between the parties pending in the Eastern District of Texas. In the Texas case, Wyeth is accused of infringing a patent owned by Alza Corporation ("Alza"), a sister company of Cordis.

. Effexor XR drug delivery system infringed Alza's U.S. Patent No. 6,440,457 to Edgren et al. (the "Edgren Patent"). Alza sued Wyeth in July 2006. Exhibit 1.

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This case should be dismissed for lack of subject matter jurisdiction because there is no diversity between the parties. Both Wyeth and Cordis are citizens of the State of New Jersey. Alternatively, this lawsuit should be dismissed or stayed in favor of Cordis' Court of Chancery suit. Retaining federal jurisdiction over this declaratory judgment action is discretionary, and is not appropriate here, where the case presents no question of federal law and the dispute between the parties can be resolved in the Court of Chancery.

II. FACTS

A. The Parties

Cordis is engaged in the business of developing, manufacturing and selling innovative medical devices. It is the world's leading developer and manufacturer of interventional cardiology, radiology and electrophysiology products for circulatory disease management. Anderson Declaration (Exhibit 4) at ¶ 2.

Cordis is a wholly owned subsidiary of Johnson & Johnson and is composed of four business units: Cordis Cardiology ("Cardiology"), Cordis Endovascular ("Endovascular"), which are divisions of Cordis Corporation; and Biosense Webster, Inc. and Cordis Neurovascular, Inc. ("Neurovascular"), which are separately-incorporated subsidiaries of Cordis Corporation. Id. at ¶ 3.

Cordis is a Florida corporation with its principal place of business in Warren, New Jersey. In addition, it has operations across the United States, including Florida, California and Puerto Rico. Id. at ¶ 16-17. It also has operations in various countries around the world, including Belgium, the Netherlands, and Mexico. Id.

Wyeth states that it is a Delaware corporation with a principal place of business in Madison, New Jersey. D.I. 1. Wyeth is engaged in the business of developing, manufacturing and selling pharmaceutical products. It does not compete with Cordis

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C. **Cordis' Cypher Stent**

Cordis developed the first drug-eluting stent, the Cypher stent, using rapamycin provided by Wyeth. Cypher has been sold and used in Europe since 2002 and was approved in the United States in April 2003.

The Cypher stent has been an overwhelming commercial success. Since its introduction in Europe in 2002, over 3.5 million Cypher stents have been implanted. Sales have reached over $ 8 billion. Exhibit 4 at ¶ 19.

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D. **Alza's Lawsuit Against Wyeth**

In late 2005 the Edgren dispute arose.

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Wyeth sells over $3 billion a year of Effexor. Exhibit 5 at p. 3.

Alza sued Wyeth in July 2006. Exhibit 1.

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G. Wyeth's Federal Lawsuit

Wyeth's complaint in this Court seeks "damages and declaratory and injunctive relief." D.I. 1 at ¶ 1. REDACTED Wyeth asserts that Cordis' actions amount to and states that "Wyeth has a present intention REDACTED Jurisdiction is claimed under 28 U.S.C. § 1332(a)(1), based on the allegations that the parties are citizens of different states. D.I. 1 at ¶ 3. As support for the diversity allegation, and contrary to the terms of the Agreement, Wyeth alleges that Cordis has "its principal place of business in Miami Lakes, Florida." D.I. 1 at ¶ 2.

Wyeth relies on the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, for its claim for declaratory relief. Id. Wyeth seeks a declaration "that Cordis' failures to meet obligations

and it seeks "a declaration of its right

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H. **Cordis' Delaware Court of Chancery Suit**

The day after Wyeth filed suit in this Court, Cordis filed an action for declaratory judgment and specific performance in Delaware Court of Chancery. Exhibit 3. In that suit, Cordis seeks an order: declaring that Wyeth is under a continuing obligation

directing Wyeth specifically to perform its obligations under the Agreement; and declaring that Cordis is not in breach or material breach of its obligations under this Agreement or that, if any breach has occurred, it has been cured. Exhibit 3 at 10.

Cordis' Court of Chancery complaint has subsequently been amended

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III. ARGUMENT

A. This Lawsuit Should be Dismissed for Lack of Subject Matter Jurisdiction

1. Third Circuit Law Requires that the Principal Place of Business of a Corporation be at the Center of Corporate Activities

Wyeth's complaint claims subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a)(1) based on diversity. D.I. 1 at ¶ 3. In fact, both Wyeth and Cordis have their principal

place of business in New Jersey. Accordingly, there is no diversity, and no basis for jurisdiction under 28 U.S.C. § 1332(c).

Under 28 U.S.C. § 1332(c), "A corporation shall be deemed to be a citizen of any State by which it has been incorporated and of the State where it has its principal place of business." According to the Complaint, Wyeth is incorporated in Delaware and has its principal place of business in Madison, New Jersey. D.I. 1 at ¶ 1. Thus, Wyeth is a citizen of Delaware and New Jersey. Cordis is incorporated in Florida and has its principal place of business in Warren, New Jersey. Cordis is a citizen of both Florida and New Jersey. Therefore, since both Wyeth and Cordis are both citizens of New Jersey, there is no diversity, and no basis for jurisdiction under 28 U.S.C. § 1332(a)(1). See, e.g., Grand Union Supermarkets of the Virgin Islands, Inc. v. H.E. Lockhart Mgmt., Inc., 316 F.3d 408, 410 (3d Cir. 2003) ("Jurisdiction under 28 U.S.C. § 1332(a)(1) requires complete diversity of the parties; that is, no plaintiff can be a citizen of the same state as any of the defendants.").

Wyeth alleges that Cordis' principal place of business is in Miami Lakes, Florida. To the contrary, as set forth in the Declaration of Cordis' Worldwide Chairman Rick Anderson, Cordis' principal place of business is in Warren, New Jersey. The burden of proving otherwise rests on Wyeth. Cf. Thomson v. Gaskill, 315 U.S. 442 (1942); Alpha Portland Cement Co. v. MacDonald Eng'g Co., 224 F. Supp. 714, 714 (E.D. Pa. 1963).

Courts of the Third Circuit apply the "center of corporate activities" test to determine the principal place of business of a party. Mennen Co. v. Atlantic Mutual Ins. Co., 147 F.3d 287, 291 (3d Cir. 1998); Quaker State Dyeing & Finishing Co. v. ITT Terryphone Corp., 461 F.2d 1140, 1143 (3d Cir. 1972); Alex v. Eckerd Drugs, 2006 WL 2372032 at *1 (W.D. Pa. Aug. 15, 2006). This test was first articulated in Kelly v. U.S. Steel Corp., 284 F.2d

850 (3d Cir. 1960). In Kelly, the Third Circuit found the principal place of business of U.S. Steel Corp. to be Pennsylvania because it was "the headquarters of day-to-day corporate activit[ies] and management." Id. at 854. The Court's analysis was driven principally by the fact that the majority of high level operating executives, including the Operation Policy Committee, were located in Pennsylvania. Factors such as location of employees and physical facilities were considered to be "of lesser importance." Id.; see also Grand Union, 316 F.3d at 411.

The Third Circuit later identified the location of these decision-making corporate executives as the most significant factor in the principal place of business inquiry:

> ***The most significant factor upon which Kelly depends is the headquarters of the day to day corporate activities and management decisions.*** It also attaches value to secondary considerations which include where the Board decisions concerning overall corporate functions are reached, and also where a number of the basic corporate functions are maintained (e.g., pension plans, insurance, loans).

Quaker State Dyeing & Finishing, 461 F.2d at 1143 (emphasis added).

"Applying the decision in Kelly, courts in this Circuit have weighed the distribution of executives and corporate officers as the primary consideration in determining a corporation's principal place of business." In re Linerboard Antitrust Litig., 2005 WL 1625040 at *6 (E.D. Pa. July 11, 2005). See also Mennen, 147 F.3d at 291; Quaker State Dyeing & Finishing, 461 F.2d at 1143.

> Moreover, consistent with the Kelly court's ruling that the location of operations is a secondary factor, courts in this Circuit have held that the location of the largest number and/or majority of executives/corporate officers qualified as the principal place of business even where a company's operations were predominantly located in another state.

In re Linerboard, 2005 WL 1625040 at *6; see also Alex, 2006 WL 2372032 at *1 ("Relevant factors of lesser importance include: (1) location of physical plants; (2) location of assets; and (3) location of employees.").

2. Under the Kelly Test, Cordis' Principal Place of Business is in Warren, New Jersey.

By their conduct, the parties have recognized that Cordis' principal place of business is in New Jersey. The Kelly test mandates the same outcome.

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The recitations in the contract are persuasive evidence of the location of the party's principal place of business. Shahmoon Indus., Inc. v. Imperato, 338 F.2d 449, 452 (3d Cir. 1964).

It is true that Cordis originated as a Florida corporation with its principal place of business in Florida. In 1996, however, Cordis was acquired by Johnson & Johnson, and since that time its center of operations has steadily moved into the State of New Jersey. Exhibit 4 at ¶ 18. As a consequence, by the year 2005, the Sixth Circuit said that "Cordis is a Florida corporation with its principal place of business in New Jersey. . . ." Stratienko v. Cordis Corp., 429 F.3d 592, 595 (6th Cir. 2005).

The question of diversity is determined as of the time the complaint is filed. Grand Union, 316 F.3d at 410. Thus, the question of Cordis' citizenship is determined as of

October, 2006. As of October 2006, the Kelly test leads to the conclusion that Cordis is a citizen of New Jersey. Focusing on "the most significant factor upon which Kelly depends," it is clear that "the headquarters of the day to day corporate activities and management decisions" is New Jersey. Quaker State Dyeing & Finishing, 461 F.2d at 1143.

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It is in New Jersey "where the Board decisions concerning overall corporate functions are reached." Quaker State Dyeing & Finishing, 461 F.2d at 1143.

Cordis also has major operations outside of Warren, including in Miami, Puerto Rico, Mexico, the Netherlands and Belgium. Id. at ¶ 12, 17.

REDACTED . Cordis maintains manufacturing operations in Miami, as well as through affiliated companies in Mexico, Puerto Rico and the Netherlands. Id. at ¶ 16.

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Under controlling Third Circuit law, factors such as "(1) location of physical plants; (2) location of assets; and (3) location of employees" are of secondary importance. Alex, 2006 WL 2372032 at *1; Kelly, 284 F.2d at 854 ("lesser importance"). The crucial analysis is to "weigh[] the distribution of executives and corporate officers as the primary consideration in determining a corporation's principal place of business." In re Linerboard, 2005 WL 1625040 at *6; see also Mennen, 147 F.3d at 291; Quaker State Dyeing & Finishing, 461 F.2d at 1143. Under the Kelly test, with 8 out of 12 Board members located in Warren, "the headquarters of day-to-day corporate activit[ies] and management," Kelly, 284 F.2d at 854, is in New Jersey. Thus, there is no diversity with Wyeth. 28 U.S.C. § 1332(a)(1). The Court should dismiss this case under Fed. R. Civ. P. 12(b)(1).

B. This Court Should Dismiss or Stay Wyeth's Complaint in Favor of the Delaware Court of Chancery Suit

1. The Law Favors Dismissal or Staying Federal Proceedings in Favor of State Court Actions

Wyeth seeks declaratory relief under the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 (the "Act"), including "a declaration of its right to terminate its agreement with Cordis." D.I. 1 at ¶ 6, 36 and ¶ b, Prayer For Relief. The District Court has discretion to determine whether to entertain such an action. Terra Nova Ins. Co. v. 900 Bar, Inc., 887 F.2d 1213, 1222-24 (3d Cir. 1989).

The Act provides that "any court of the United States, upon filing of an appropriate pleading, *may* declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201 (emphasis added). As this Court has recognized, the use of the permissive "may" in the Act "gives federal district courts statutory discretion in deciding whether to entertain a declaratory judgment action." Century Indem. Co. v. Pyrites Co., 2003 WL 22283500 at *2 (D. Del. Oct. 2, 2003).

Thus, even if this Court determines it has diversity jurisdiction, it is "under no compulsion to exercise that jurisdiction." Brillhart v. Excess Ins. Co. of America, 316 U.S. 491, 494 (1942); Wilton v. Seven Falls Co., 515 U.S. 277, 287 (1995) ("We have repeatedly characterized the Declaratory Judgment Act as 'an enabling Act, which confers a discretion on the courts rather than an absolute right upon the litigant.'" (quoting Public Serv. Comm'n of Utah v. Wycoff Co., 344 U.S. 237, 241 (1952))). The question whether to exercise jurisdiction over a declaratory judgment action is within the discretion of a federal court. Brillhart, 316 U.S. at 494. Where there are duplicative proceedings, the court must exercise its discretion to avoid piecemeal litigation. Wilton, 515 U.S. at 281.

The Supreme Court has cautioned district courts against assuming jurisdiction over declaratory judgment cases, where, as here, the dispute does not implicate federal law and another action is pending in a state court.

> Ordinarily it would be uneconomical as well as vexatious for a federal court to proceed in a declaratory judgment suit where another suit is pending in a state court presenting the same issues, not governed by federal law, between the same parties. Gratuitous interference with the orderly and comprehensive disposition of a state court litigation should be avoided.

Brillhart, 316 U.S. at 495. Where a suit is pending in state court "involving the same parties and presenting opportunities for ventilation of the same state law issues, a district court might be indulging in 'gratuitous interference' if the federal declaratory action is permitted to proceed." Intravascular Research Ltd. v. Endosonics Corp., 994 F. Supp. 564, 574 (D. Del. 1998) (quoting Wilton, 515 U.S. at 283).

The Supreme Court in Brillhart set forth a number of factors indicating whether the district court should exercise its discretion in proceeding in a declaratory judgment action:

> Where a district court is presented with a claim such as was made here, it should ascertain whether the questions in controversy between the parties to the federal suit, and which are not foreclosed under the applicable substantive law, can be better settled in the proceeding pending in the state court. This may entail inquiry into the scope of the pending state court proceeding and the nature of [the] defenses open there. The federal court may have to consider whether the claims of all parties in interest can satisfactorily be adjudicated in that proceeding, whether [all] necessary parties have been joined, whether such parties are amenable to process in that proceeding, etc.

Brillhart, 316 U.S. at 495. The Third Circuit set forth additional general guidelines for the exercise of discretion under the Act:

> (1) the likelihood that the declaration will resolve the uncertainty of obligation which gave rise to the controversy;
>
> (2) the convenience of the parties;

(3) the public interest in a settlement of the uncertainty of obligation; and

(4) the availability and relative convenience of other remedies.

Terra Nova, 887 F.2d at 1224 (citations omitted); accord, Century Indem. Co., 2003 WL 22283500 at *2.

2. **The Factors in This Case Mandate Dismissal or a Stay**

The factors surrounding Wyeth's district court declaratory judgment action favor dismissal or a stay in favor of the co-pending Court of Chancery suit.

The first Terra Nova factor clearly favors dismissal in favor of the Court of Chancery proceedings. Wyeth's complaint presents no question of substantive federal law. The only legal question is one of New Jersey state contract law. Thus, there is "no federal interest in resolving this dispute in a federal court rather than in a state court." Nat'l Union Fire Ins. Co. of Pittsburgh v. Freeport-McMoran, Inc., 767 F. Supp. 568, 572 (D. Del. 1991); U.S. Surgical Corp. v. Litvack, 1999 WL 33220034 at *4 (D. Del. Dec. 30, 1999) ("it is important to note that the governing law in this case is not federal law."); Intravascular Research, Ltd., 994 F. Supp. at 574 ("[B]ecause state law governs . . ., there is no federal interest in maintaining jurisdiction over this action."); American Home Assurance Co. v. Church of Bible Understanding, 2004 WL 1964906 at *4 (E.D. Pa. Aug. 16, 2004) ("This case presents only issues of state worker's compensation and contract law and does not implicate federal law."); St. Clair Intellectual Prop. Consultant, Inc. v. Mirage Systems, Inc., 419 F. Supp. 2d 620, 624 (D. Del. 2006) (dismissing because, *inter alia*, "state court is a better forum for consideration of state law contract issues.").

Indeed, the Court of Chancery sits precisely to resolve such controversies. The Delaware Court of Chancery is the premier court in the United States for corporate disputes such as this one. As explained by the late Chief Justice William Rehnquist:

> The Delaware state court system has established its national preeminence in the field of corporation law due in large measure to its Court of Chancery. Because the Court of Chancery, by design, has no jurisdiction over criminal and tort cases -- matters which create huge backlogs in other judicial systems -- corporate litigation can proceed quickly and effectively. ... Corporate lawyers across the United States have praised the expertise of the Court of Chancery .... ***[W]e need to reaffirm the view that our state and federal judicial systems are one resource, and an increasingly scarce one at that. The nation can no longer afford the luxury of state and federal systems that work at cross-purposes or irrationally duplicate each other's efforts.***

William H. Rehnquist, "The Prominence of the Delaware Court of Chancery in the State-Federal Joint Venture of Providing Justice," Speech at the Bicentennial of the Delaware Court of Chancery, 48 Bus. Law. 351, 354-55 (1992) (emphasis added). Exhibit 11.

All the relief that Wyeth seeks in this case is available to it in the Court of Chancery.

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To the extent that Wyeth is seeking damages, the Court of Chancery has power to grant damages to Wyeth. See Gesoff v. IIC Indus., Inc., 902 A.2d 1130, 1154 (Del. Ch. 2006) ("In determining damages, the court's 'powers are complete to fashion any form of equitable and monetary relief as may be appropriate ....'") (quoting Weinberger v. UOP, 457 A.2d 701, 714 (Del. 1983)); see also Eureka VIII LLC v. Niagara Falls Holdings LLC, 899 A.2d 95, 107 (Del. Ch. 2006) ("If a contract or agreement is silent as to the remedy for a breach, the 'Court of

Chancery has the discretion to award any form of legal and/or equitable relief and is not limited to awarding contract damages for breach of the agreement.'") (citation omitted).[1]

In light of the expertise of the Court of Chancery in contractual matters such as this one, this case should be dismissed or stayed in favor of Cordis' Court of Chancery action. Cf. Century Indem. Co., 2003 WL 27283500 at *2 ("Considering the first and second Terra Nova factors, the court does not agree with Century that it is better able to determine Century's obligations under the policies than the Philadelphia Court of Common Pleas."); U.S. Surgical, 1999 WL 33220034 at *3 (dismissing complaint because "it does not seem that the legal issues in this case are so complex or involve such unique aspects of Delaware law that the California court will be unable to properly address them.").

The remaining Terra Nova factors are either neutral or favor Cordis. Not surprisingly, in light of the discretion written into the Act and the Supreme Court's admonitions to district courts to avoid assuming jurisdiction over declaratory judgment cases where there is another action pending in a state court, the general rule is that the courts abstain even where some Terra Nova factors are only neutral. See American Home Assurance, 2004 WL 1964906 at *4 (stay granted where, *inter alia*, "the federal forum is no more or less convenient than the state forum [and] there is no particular public interest in [the] case"); U.S. Surgical, 1999 WL 33220034 at *5.

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[1] The fact that the complaint is not limited to declaratory relief does not preclude abstention in favor of a state court proceeding. See ACandS, Inc. v. Aetna Cas. and Sur. Co., 666 F.2d 819, 823 (3d Cir. 1981); St. Clair, 419 F. Supp. 2d at 622 ("Plaintiff filed the instant action, asking the Court to declare it the owner of [certain] patents and also alleging various tort injuries;" dismissed in favor of state proceedings after Terra Nova analysis); Remington Arms Co. v. Liberty Mut. Ins. Co., 748 F. Supp. 1057 (D. Del. 1990) (plaintiff sought a declaration as to indemnification and damages arising from defendant's refusal to indemnify; stay in favor of state proceedings denied after Terra Nova analysis).

The general rule of abstention is especially strong where, as here, no issue of federal law is implicated. In Century Indem. Co., where there was only state law in issue, this Court dismissed because it was not "*better* able to determine Century's obligations under the policies than the Philadelphia Court of Common Pleas"; that all necessary parties had been joined in both actions; that this court was not the "*more* convenient forum"; that this court did not have "any *greater* interest" in adjudicating the case; and that all the remedies that might be sought by the parties were available in either court. Century Indem. Co., 2003 WL 22283500 at *2, *3 (all emphases added).

Here, the analysis is much the same. There is no federal law implicated in this case. The only issue is state contract law. The federal court is not "better able" to declare the rights of the parties than is the Court of Chancery. All the interested parties are named in both cases and Wyeth has agreed to jurisdiction of the Court of Chancery. D.I. 1, Exhibit A at Section 13.7. American Home Assurance, 2004 WL 1964906 at *4. The Court of Chancery is equally convenient to the parties. Century Indem. Co., 2003 WL 22283500 at *3. Moreover, the public interest in resolving this dispute is served as easily in the Court of Chancery as in district court. U.S. Surgical, 1999 WL 33220034 at *5; Century Indem. Co., 2003 WL 22283500 at *3 ("[T]he court does not deem that the District of Delaware has any greater interest in adjudicating the instant case than the State of Pennsylvania.").

Wyeth may argue that it is entitled to proceed in district court because it was first to file (by a day). However, the Third Circuit has instructed the district courts to "look with disapproval upon any attempt to circumvent the laudable purposes of the Act, and seek to prevent the use of the declaratory action as a method of procedural fencing, or as a means to provide another forum in a race for res judicata." Terra Nova, 887 F.2d at 1225 (citations

omitted). The discretionary nature of the Declaratory Judgment Act does not turn on which litigant was first to reach the court room:

> "[T]he discretion of a federal court [to entertain a declaratory judgment action] should not turn on so mechanical a rule." Instead, "[t]he real question . . . is not which action was commenced first but which will most fully serve the needs and convenience of the parties and provide a comprehensive solution for the general conflict."

U.S. Surgical, 1999 WL 33220034 at *5 (citations and internal quotations omitted).

All the Terra Nova factors favor the dismissal or stay of this case in favor of Cordis' co-pending Court of Chancery Action. Cf. Terra Nova, 887 F.2d 1213, 1222-24; Century Indem. Co., 2003 WL 22283500 at *2; U.S. Surgical, 1999 WL 33220034; American Home Assurance, 2004 WL 1964906; St. Clair, 419 F. Supp. 2d 620.

CONCLUSION

For the reasons set forth above, this Court should grant Cordis' motion for dismissal under Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction, or, in the alternative, for dismissal or stay in favor of the co-pending state court action in the Delaware Court of Chancery.

Dated: November 16, 2006

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EXHIBIT 1

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
LUFKIN DIVISION

ALZA CORPORATION, a Delaware corporation,

Plaintiff,

v.

WYETH, a Delaware corporation, and WYETH PHARMACEUTICALS, INC., a Delaware corporation,

Defendants.

C.A. No. 9:06cv156

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Alza Corporation ("Alza"), by its undersigned counsel, brings this action for patent infringement against defendants Wyeth and Wyeth Pharmaceuticals, Inc. (collectively "Defendants") and alleges as follows:

Jurisdiction and Venue

1. This action is based upon the Patent Laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 6,440,457 ("the '457 Patent").

2. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

3. Venue properly lies in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

4. This Court has personal jurisdiction over Defendants.

Parties

5. Alza is a Delaware corporation with a principal place of business at 1900 Charleston Road, Mountain View, California 94039.

6. On information and belief, Wyeth is a Delaware corporation with a principal place of business at Five (5) Giraldo Farms, Madison, New Jersey 07940.

7. On information and belief, Wyeth Pharmaceuticals, Inc., is a Delaware corporation with a place of business at 500 Arcola Road, Collegeville, Pennsylvania 19426.

8. On information and belief, Wyeth Pharmaceuticals, Inc., is a subsidiary of Wyeth.

9. On information and belief, at least in part for its own benefit, Wyeth directed, authorized, assisted, cooperated with, or participated in the acts of Wyeth Pharmaceuticals, Inc., about which Alza complains.

Claim of Patent Infringement

10. Alza realleges paragraphs 1 through 9 above as if fully set forth herein.

11. On August 27, 2002, the '457 Patent, entitled "Method of Administering Antidepressant Dosage Form," was duly and legally issued by the United States Patent and Trademark Office to Alza as the assignee of the inventors, David Emil Edgren, Gurdish Kaur Bhatti, Zahedeh Hatamkhani, and Patrick S. L. Wong. The '457 Patent remains in full force and effect and will expire no earlier than August 27, 2019. A true and correct copy of the '457 Patent is attached to this Complaint as Exhibit A.

12. Alza has been and remains the owner of all right, title, and interest in and to the '457 Patent.

13. On information and belief, Defendants contributorily infringe and induce infringement of Claim 1 of the '457 Patent under 35 U.S.C. § 271, including but not limited to

§§ 271(b)-(c) and (f). Defendants contributorily infringe and induce infringement of the '457 Patent through various activities including but not limited to the manufacture, use, sale, and offer for sale of Effexor® XR products in the United States after the '457 Patent issued.

14. On information and belief, Defendants knew of the '457 Patent at all relevant times before making, using, selling, or offering for sale Effexor® XR products.

15. On information and belief, Defendants have in the past offered for sale and sold, and continue to offer for sale and sell Effexor® XR products that constitute a material part of the invention claimed in the '457 Patent and that have no substantial use other than as an infringement of the '457 Patent.

16. On information and belief, Defendants knew and intended that purchasers of Effexor® XR products would use the products in methods so as to infringe the '457 Patent.

17. On information and belief, Defendants have actively induced purchasers of Effexor® XR products to use the products in methods so as to infringe the '457 Patent.

18. On information and belief, purchasers of Effexor® XR products use the products in methods so as to infringe the '457 Patent.

19. On information and belief, Defendants have in the past willfully infringed, and continue to willfully infringe, the '457 Patent through their manufacture, use, sale, and offer for sale of Effexor® XR products.

Prayer For Relief

WHEREFORE, Alza prays for a judgment against Defendants as follows:

(a) adjudging that Defendants have infringed the '457 Patent under 35 U.S.C. § 271;

(b) ordering Defendants to account for and pay to Alza all damages caused to Alza by reason of Defendants' infringement of the '457 Patent, together with prejudgment interest on all damages;

(c) increasing the damages three times based on the willful nature of Defendants' infringement under 35 U.S.C. § 284;

(d) granting Alza its reasonable attorney fees under 35 U.S.C. § 285; and

(e) for such further and additional relief as this Court deems just and proper.

Date: July 26, 2006

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Exhibit A

U.S. Patent No. 6,440,457

US006440457B1

(12) **United States Patent**
Edgren et al.

(10) **Patent No.: US 6,440,457 B1**
(45) **Date of Patent: Aug. 27, 2002**

(54) **METHOD OF ADMINISTERING ANTIDEPRESSANT DOSAGE FORM**

(75) Inventors: **David Emil Edgren**, El Granada; **Gurdish Kaur Bhatti**; **Zahedeh Hatamikhani**, both of Fremont; **Patrick S. L. Wong**, Palo Alto, all of CA (US)

(73) Assignee: **Alza Corporation**, Mountain View, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(52) U.S. Cl. 424/468; 424/457; 424/473; 514/964; 514/654

(58) Field of Search 424/473, 468, 424/457; 514/964, 654

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Primary Examiner—Edward J. Webman
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(57) ABSTRACT

The invention pertains to a dosage form 10 and to administering an antidepressant medicament 16 for an extended period of time in a rate-known dose.

1 Claim, 1 Drawing Sheet

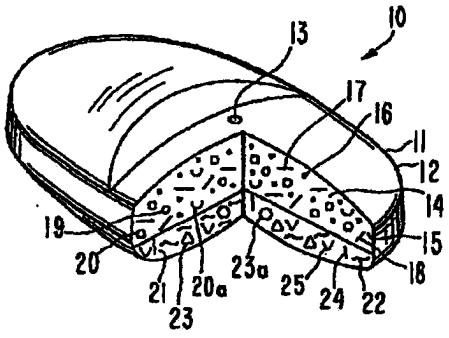


FIG. 1

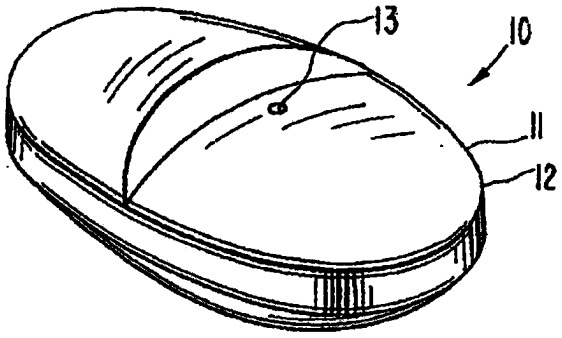


FIG. 2

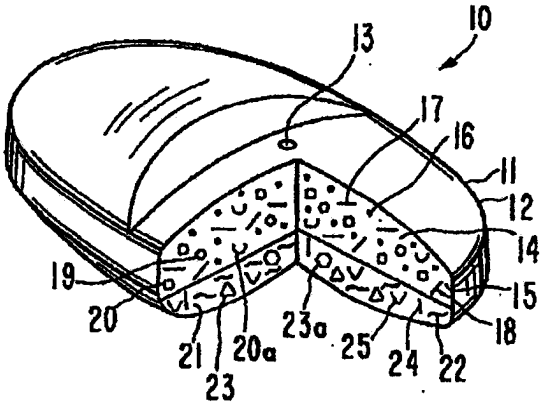
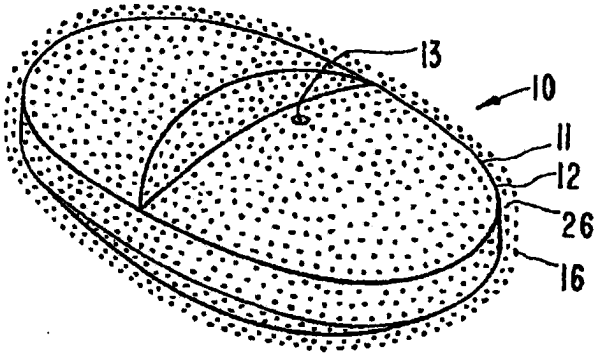


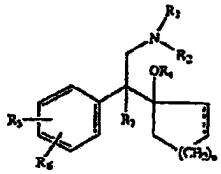
FIG. 3



METHOD OF ADMINISTERING ANTIDEPRESSANT DOSAGE FORM

FIELD OF THE INVENTION

This invention pertains to a controlled-release dosage form comprising a compound of the following structural formula:



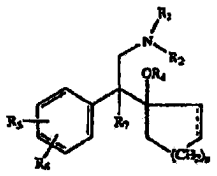
useful for antidepressant therapy. The invention concerns also a method useful for antidepressant therapy by administering the controlled-release dosage form comprising the compound of the formula.

BACKGROUND OF THE INVENTION

The primary goal of drug administration is to provide a therapeutic dose of drug in the body to achieve a desired blood concentration, and then maintain the desired drug blood concentration. The prior art, in attempts to obtain the desired therapeutic effect, often used different dosage forms or programs. One dosage program consists of a single dosing of the drug from a conventional capsule or tablet that produced a rapid rise followed by an immediate decline of the drug blood level versus time. The single dosing does not maintain the drug within a therapeutic range for an extended period of time, but exhibits of a short duration of action due to the inability of the conventional dosage form to provide drug delivery over time.

Another prior art dosing program used to obtain and to achieve drug blood levels consists in administering the drug repetitively using conventional dosage forms at various dosing intervals, as in multiple-dose therapy. In administering a drug according to the multiple-dose therapy, the drug blood level reached and the time required to reach that level depends on the dose and the dosing interval. There are, however, several potential problems inherent in multiple dose therapy. For example, if the dosing interval is not appropriate for the biological half-life of the drug, large peaks and valleys may result in the drug blood levels. Also, the drug blood level may not be within the therapeutic range at sufficiently early times, an important consideration for many disease states. And too, patient noncompliance with the multiple dosing regimen can result in a failure of this approach, especially as a drug in circulation surges to a high each time the drug is administered followed by a decline in drug concentration in the blood and in body compartments. Thus, a graph of drug in circulation following a dosage program of several doses, has an appearance of a series of peaks:, which may surpass the toxic threshold. Then, each time the blood levels decreases into valleys, below a critical level needed to achieve a desired therapeutic effect, that effect may not be obtainable in the blood and body. Conventional dosage forms and their mode of operation are discussed in *Remington's Pharmaceutical Sciences*, 18th Edition, pages 1676 to 1686, (1990), Mack Publishing Co.; *The Pharmacological Basis of Therapeutics*, 7th Edition, page 7 (1985) published by MacMillian Publishing Co., and in U.S. Pat. Nos. 3,598,122 and 3,598,123 both issued to Zaffaroni.

A critical need exists for a controlled-rate dosage form for administering the drug of the formula:



which drug is presently administered in conventional dosage forms including tablets, capsules, elixirs and suspensions. These conventional dosage forms produce the peaks and valleys drug pattern presented above and they do not provide for controlled-rate therapy over an extended period of time. The drug of the formula is dosed twice or thrice a day now because of its elimination half-life of three to five hours. This pattern of dosing indicates the need for a controlled-release dosage form that can administer the drug at a controlled rate over an extended time to provide constant therapy and thereby eliminate the need for multiple dosing. The drugs of the structural formula are known in U.S. Pat. Nos. 4,535,186; 4,611,078; and 4,761,501 all issued to Husbands, Yardley and Muth.

The prior art provided controlled-release dosage forms that can continuously over time administer a drug for controlled-rate therapy. For example, in U.S. Pat. No. 4,327,725 issued to Cortese and Theeuwes and in U.S. Pat. Nos. 4,612,008; 4,765,989; and 4,783,337 issued to Wong, Barclay, Deters, and Theeuwes. The dosage forms disclosed in these patents provide a drug at a constant rate for effecting a therapeutic range for preferred therapy. The dosage forms of the patents provide a therapeutic range and avoids delivering the drug in excess in a toxic range with its accompanying side-effects. The dosage forms of the patents in providing a controlled dose in a therapeutic range also avoids delivering the drug in an ineffective dose in an ineffective range.

The dosage forms presented immediately above operate successfully for their intended use and they can deliver many drugs indicated for good therapy. The drugs of the above structural formula, however, possess properties such as a high solubility of 570 mg per ml at a body temperature of 37° C. that can lead to a premature release of the drug from the dosage form. During operation of the dosage forms, the convection motion of the imbibed fluid, and the hydrostatic pressure of the imbibed fluid coupled with the high solubility can result in the premature release of the drugs of the formula.

It is immediately apparent in the light of the above presentation that an urgent need exists for a dosage form endowed with controlled-release delivery for delivering the drugs embraced by the structural formula. The need exists for the dosage form for delivering the drug at a controlled dose in a therapeutic range while simultaneously providing the intended therapy. It will be appreciated by those versed in the dispensing art, that such a dosage form that can administer the drug in a controlled-rate dose over time, would, represent an advancement and a valuable contribution to the art.

OBJECTS OF THE INVENTION

Accordingly, in view of the above presentation, it is an immediate object of this invention to provide a dosage from

that possesses controlled-release delivery for providing a dosage form for administering a drug of the structural formula.

Another object of the present invention is to provide a dosage form for administering the drug of the formula in a controlled-rate dose in a therapeutic range over a prolonged period of time.

Another object of the present invention is to provide a dosage form that can deliver the drug of the formula essentially-free of a premature release from the dosage form.

Another object of the present invention is to provide a drug delivery controlled-release system that can deliver a drug for maintaining constant drug levels in the blood thereby functioning as a prolonged release system.

Another object of the present invention is to provide drug delivery sustained-release system that provides slow release of the drug over an extended period of time optionally in a therapeutic range.

Another object of the present invention is to provide a dosage form that substantially reduces and/or substantially eliminates the unwanted influences of a gastrointestinal environment of use and still provides controlled drug administration.

Another object of the present invention is to provide an improvement in a dosage form for administering a drug embraced by the structural formula and its pharmaceutically acceptable salt, wherein the improvement comprises delivering the drug in a controlled-release rate from the dosage form for improved and known therapy.

Another object of the invention is to provide a once-a-day controlled-release dosage form to deliver the drug of the structural formula orally to a patent in need of therapy.

Another object of the invention is to provide a method for administering a drug of the formula by orally administering the drug in a controlled rate dose per unit dose over an extended time to an animal in need of therapy.

Another object of the present invention is to provide a method for administering a drug of the formula in a therapeutic range while simultaneously substantially-avoiding a toxic range and an infective range.

Another object of the present invention is to provide a therapeutic composition comprising a drug of the structural formula blended with a drug-composition forming polymer.

Another object of the invention is to provide a therapeutic composition comprising a member selected from the group consisting of venlafaxine and its pharmaceutically acceptable additional salt and a pharmaceutically acceptable polymer carrier for venlafaxine and its acceptable salts.

Other objects, feature, and advantages of the invention will more apparent to those versed in the dispensing arts from the following detailed specification, taken in conjunction with the drawings and the accompanying claims.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawing figures, which are not drawn to scale, but are set forth to illustrate various embodiments of the invention, the drawing figures are as follows:

Drawing FIG. 1 is a general view of a dosage form provided by the invention, which dosage form is designed and shaped for oral administration, and for a drug delivery in a controlled-rate dose in the gastrointestinal tract;

Drawing FIG. 2 is an opened view of the dosage form of drawing FIG. 1 for depicting the structure of the dosage form and the composition member contained inside the dosage form; and

Drawing FIG. 3 is a view of a dosage form that depicts an external, instant-release of drug of the structural formula coated on the exterior surface of the dosage form.

In the drawing figures, and in the specification, like parts in related figures are identified by like numbers. The terms appearing earlier in the specification and in the description of the drawing figures, as well as embodiments thereof, are further described elsewhere in the disclosure.

DETAILED DESCRIPTION OF THE DRAWINGS

Turning now to the drawing figures in detail, which drawing figures are examples of dosage forms provided by this invention, and which examples are not to be construed as limiting, one example of a dosage form is seen in drawing FIG. 1. In drawing FIG. 1, a dosage form 10 is seen comprising a body member 11, which body 11 comprises wall 12, that surrounds and forms an internal area, not seen in drawing FIG. 1. Dosage form 10 comprises at least one exit port 13 for connecting the exterior with the interior of dosage form 10.

The dosage form 10 of drawing FIG. 1 illustrates a controlled-release dosage form manufactured as an osmotic dosage form that delivers a drug by osmotic action over an extended period of time. The dosage form comprising controlled-release properties embraced by this invention are successful at maintaining substantially constant drug levels in the blood or in a tissue. The dosage forms within the mode and manner of this invention comprises also sustained-release dosage forms. The sustained-release dosage forms releases the drug and provide drug levels in the blood or target tissue within a therapeutic range over an extended period of time. The invention embraces additionally prolonged release dosage forms. The prolonged release dosage form denotes extended duration of drug delivery action over that achieved by conventional drug delivery.

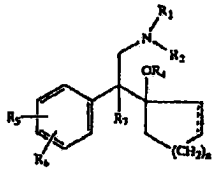
In drawing FIG. 2, dosage form 10 of FIG. 1 is seen in opened section. In drawing FIG. 2, dosage form 10 comprises a body 11, a wall 12 that surrounds and defines an internal compartment 14. In drawing FIG. 2, internal compartment 14 communicates through an exit passageway 13 with the exterior of dosage form 10.

Wall 12 of dosage form 10 comprises totally or in at least a part of a composition that is permeable to the passage of an exterior fluid present in an environment of use, such as aqueous and biological fluids. Wall 12 is formed of nontoxic ingredients, is substantially impermeable to the passage of a drug and other ingredients present in compartment 14. Wall 12 comprises a composition that is substantially inert, that is, wall 12 maintains its physical and chemical integrity during the drug dispensing life of a drug from dosage form 10. The phrase, "maintaining its physical and chemical integrity," means wall 12 does not lose its structure and it does not change during the dispensing life of dosage form 10, except for possible leaching of one or more exit 13 passageway formed during operation of dosage form 10 or for leaching a water-soluble flux enhancers blended into wall 12. Wall 12 comprises a material that does not adversely affect an animal, a human or any other components comprising the dosage form. Representative materials for forming wall 12, are in one embodiment, a cellulose ester polymer, a cellulose ether polymer and a cellulose esterether polymer. These cellulosic polymers have a degree of substitution. D.S., on the anhydroglucose unit, from greater than 0 up to 3 inclusive. By degree of substitution is meant the average number of hydroxyl groups originally present on the anhydroglucose unit comprising the cellulose polymer that are replaced by a

substituting group. Representative materials include a member selected from the group consisting of cellulose acylate, cellulose diacylate, cellulose triacylate, cellulose acetate, cellulose diacetate, cellulose triacetate, mono-, di- and tricellulose alkanylates, mono-, di-, and tricellulose aroylates, and the like. Exemplary polymers include cellulose acetate having a D.S. up to 1 and an acetyl content up to 21%; cellulose acetate having a D.S. of 1 to 2 and an acetyl content of 21 to 35 %; cellulose acetate having a D.S. of 2 to 3 and an acetyl content of 35 to 44.8%, and the like. More specific cellulosic polymers include cellulose propionate having a D.S. of 1.8 and a propyl content of 39.2 to 45% and a hydroxyl content of 2.8 to 5.4%; cellulose acetate butyrate having a D.S. of 1.8, an acetyl content of 13 to 15% and a butyryl content of 34 to 39%; cellulose acetate butyrate having an acetyl content of 2 to 29%, a butyryl content of 17 to 53% and a hydroxyl content of 0.5 to 4.7; cellulose triacylates having a D.S. of 2.9 to 3 such as cellulose trivalerate, cellulose trilaurate, cellulose tripalmitate, cellulose trisuccinate, and cellulose trioctanoate; cellulose diacylates having a D.S. of 2.2 to 2.6 such as cellulose disuccinate, cellulose dipalmitate, cellulose dioctanoate, cellulose dipentanoate, co-esters of cellulose such as cellulose acetate butyrate and cellulose acetate propionate, and the like.

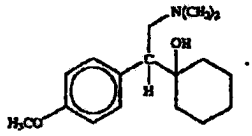
Additional polymers include ethyl cellulose of various degree of etherification with ethoxy content of from 40% to 55%, acetaldehyde dimethyl cellulose acetate, cellulose acetate ethyl carbamate, cellulose acetate methyl carbamate, cellulose acetate diethyl aminoacetate, semipermeable polyamides; semipermeable polyurethanes; semipermeable sulfonated polystyrenes; semipermeable cross-linked selective polymers formed by the coprecipitation of a polyanion and a polycation as disclosed in U.S. Pat Nos. 3,173,876, 3,276,586, 3,541,005; 3,541,006, and 3,546,142; semipermeable polymers as disclosed by Loeb and Sourirajan in U.S. Pat. No. 3,133,132; semipermeable lightly cross-linked polystyrene derivatives, semipermeable cross-linked poly (sodium styrene sulfonate); semipermeable cross-linked poly(vinylbenzyltrimethyl ammonium chloride); semipermeable polymers exhibiting a fluid permeability of 2.5×10^{-8} to 2.5×10^{-4} (cm^2/hr.atm) expressed per atmosphere of hydrostatic or osmotic pressure difference across the semipermeable wall. The polymers are known to the art in U.S. Pat. Nos. 3,845,770; 3,916,899; and 4,160,020; and in *Handbook of Common Polymers* by Scott, J. R. and Roff, W. J., 1971 published by CRC Press, Cleveland, Ohio.

Compartment 14 comprises a drug composition, identified as drug layer 15 which contains drug 16, identified by dots. Drug 16 comprises a drug of the following structural formula:



wherein the dotted line represents optional unsaturation or a cycloalkenyl moiety; R_1 is a member selected from the group consisting of hydrogen and alkyl of 1 to 6 carbon atoms; R_2 is a member selected from the group consisting of hydrogen and alkyl of 1 to 6 carbon atoms; R_4 is a member selected from the group consisting of hydrogen, alkyl of 1 to 6 carbon atoms, formyl, and alkanoyl of 2 to 7 carbon atoms; R_5 and R_6 are independently a member selected from the group consisting of hydrogen, hydroxyl, an alkyd of 1 to 6 carbon atoms, an alkoxy of 1 to 6 carbon atoms, alkanoyloxy of 2 to 7 carbon atoms, nitro, alkylmercapto of 1 to 6 carbon atoms, amino, alkylamino of 1 to 6 carbon atoms in which each alkyl group comprises 1 to 6 carbon atoms, alkanamido of 2 to 7 carbon atoms, halo, and trifluoroethyl, R_7 is a member selected from the group consisting of hydrogen and alkyl of 1 to 6 carbons, and n is one of the integers 0, 1, 2, 3, and 4. The formula embraces also the pharmaceutically acceptable addition salts including a member selected from the group consisting of inorganic, organic, hydrochloric, hydrobromic, gluconic, fumaric, maleric, sulfonic, succinic, sulfuric, phosphoric, tartaric, acetic, propionic, citric, oxalic and similar pharmaceutically acceptable addition salts. The compounds are known in U.S. Pat. Nos. 4,535,186; 4,611, 078; 4,761,501; and 5,190,765.

The drugs of the structural formula are represented by the drug 1-[2-(dimethylamino)-1-(4-methoxyphenyl)ethyl] cyclohexanol of the structural formula:



The drug embraced by the formula possesses antidepressant properties. The drug in vitro prevents the neuronal uptake of serotonin, norepinephrine, and dopamine and it does not inhibit monoamine oxidase. The drug antagonizes reserpine-induced hypothermia and potentiates the effects of levodopa, and reduces histamine-induced corticotropin release and induces cyclicadenosine monophosphate subsensitivity after both acute and chronic administration. The drug possesses excellent antidepressant activity in humans. The therapeutic amount of drug 16 in dosage form 10 is 0.5 mg to 750 mg, with individual dosage forms comprising 2, 5, 10, 25, 40, 50, 75, 100, 150, 250, 300, 500, and 600 mg of drug 16 for administering in a single dose or in more then one dose over an extended period of 24 hours. The therapeutic properties of the drug embraced by the structural formula are reported in *Current Therapeutic Research*, Vol. 42, No. 5, pages 901 to 909 (1987).

Composition 15 comprising drug 16 may comprise a drug dispensing carrier and composition formulating member consisting of a member selected from the group consisting of 0 wt % to 25 wt % of a hydroxypropylalkylcellulose where alkyl consists of 1 to 7 carbons selected from the group consisting of methyl, ethyl, isopropyl, butyl, pentyl, and hexyl which cellulose member comprises a 9,000 to 1,250,000 molecular weight and is exemplified by hydroxypropylmethylcellulose, hydroxypropylethylcellulose, hydroxypropylisopropylcellulose, hydroxypropylbutylcellulose and hydroxypropylhexylcellulose represented by dashes 17; a member selected from the group consisting of 0 wt % to 20 wt % hydroxylalkylcellulose where alkyl is 1 to 6 carbons including methyl, ethyl, propyl, butyl, pentyl, and hexyl which cellulose member comprises a 7,500 to 750,000 molecular weight and is exemplified by hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxyisopropylcellulose and

hydroxybutylcellulose as represented by slanted line 18; a member selected from the group consisting of 0 wt % to 35 wt % of a vinyl-polymer having a 3,500 to 750,000 molecular weight represented by poly-n-vinylamide, poly-n-vinylacetamide, poly-n-vinylethylacetamide, poly-n-vinylmethylpropionamide, poly-n-vinyl ethylpropionamide, poly-n-vinylmethylisobutyramide, poly-n-vinyl-2-pyrrolidone, poly-n-vinypiperidone also known as polyvinylpyrrolidone and as poly-n-vinylpyrroledone, poly-n-vinylcaprolactam, poly-n-vinyl-5-methyl-2-pyrrolidone and poly-n-vinyl-3-methyl-2-pyrrolidone, and poly-n-vinylpyrrolidone copolymer with a member selected from the group consisting of vinyl acetate, vinyl alcohol, vinyl chloride, vinyl fluoride, vinyl butyrate, vinyl laurate and vinyl stearate represented by small circles 19; and 0 wt %, where wt % is weight percent, 35 wt % of a maltodextrin polymer composition comprising the formula $(C_6H_{12}O_5)_n H_2O$ wherein n is 3 to 7,500 and the maltodextrin polymer comprises a 500 to 1,250,000 number average molecular weight represented by a small square 20; as member selected from the group consisting of 0 wt % to 40 wt % of poly(ethelyn oxide) having a molecular weight of 100,000 to 600,000 grams per mole, represented by half-circles 20a. Composition 15 optionally comprises from 0 to 4.5 wt % of a lubricant represented by magnesium stearate, calcium stearate or stearic acid. The total weight of all ingredients in composition 15 is equal to 100 wt %, weight percent.

Compartment 14 comprises a displacement composition or push layer 21. Displacement composition 21 comprises a polymer member selected from the group consisting of a polymer possessing a repeating molecular unit $-(O-CH_2CH_2)_n-$ wherein n is a positive whole number of 50,000 to 300,000 as represented by a poly(alkylene oxide) comprising poly(ethylene oxide) seen as wavy line 22; a maltodextrin polymer of the formula $(C_6H_{12}O_5)_n H_2O$ wherein n is 50 to 62,000 and comprises a 9,000 to 10,000,000 molecular weight and represented by triangle 23; a carboxymethylcellulose polymer comprising a 10,000 to 5,000,000 molecular weight represented by alkali carboxymethylcellulose, sodium carboxymethylcellulose and potassium carboxymethylcellulose, ammonium carboxymethylcellulose, sodium carboxymethyl-2-hydroxyethylcellulose, sodium carboxymethylmethylcellulose, alkali carboxymethyl-hydroxypropylmethylcellulose, alkali carboxymethyl-2-hydroxyethylmethylcellulose, alkali carboxymethyl-2-hydroxybutylmethylcellulose, alkali carboxymethyl-2-hydroxyethyl-ethylcellulose and alkali carboxymethyl-2-hydroxypropylcellulose, where alkali is sodium and potassium and seen in drawing FIG. 2 as hexagonal 23a. The polymers in push layer 21 provide unforeseen operating advantages as the polymer maintains its chemical composition during operation as it imbibes an external aqueous fluid including biological fluid while simultaneously pushing the drug from the dosage form essentially-free of substantially mixing the drug composition with the push composition. The displacement composition 21 comprises optionally from 4 to 35 wt % of an osmotically active compound, also known as osmagent and represented by vertical line 24. Representative of osmotically effective compounds comprises salts, oxides, esters that exhibit imbibition properties, carbohydrates and acids including a member selected from the group consisting of magnesium sulfate, magnesium chloride, sodium chloride, lithium chloride, potassium chloride, potassium sulfate, sodium sulfate, sodium sulfite, lithium sulfate, ammonium chloride, potassium lactate, mannitol, urea,: magnesium succinate, tartaric acid, raffinose, sorbitol, sucrose, fructose, and glucose. Displacement layer 21 optionally comprises 0.5 wt % to 30 wt % of a cellulose polymer 25 represented by the letter v. Representative of cellulose polymer 25 comprise a member selected from the group consisting of hydroxypropylcellulose, hydroxypropylmethylcellulose, hydroxypropylethylcellulose, hydroxypropylisopropylcellulose, hydroxypropylbutylcellulose, hydroxypropylpentylcellulose, and hydroxypropylhexylcellulose comprising a 9,000 to 225,000 molecular weight. The displacement composition optionally comprises 0 wt % to 5 wt % of lubricant stearic acid and, magnesium stearate, calcium oleate, oleic acid, and caprylic acid. The polymers are known in U.S. Pat Nos. 3,845,770; and 4,160,020; in *Handbook of Common Polymers* by Scott, J. R., and Roff, W. J., published by CRC Press, Cleveland, Ohio.

Dosage form 10, a seen in drawing FIG. 3 depicts another preferred manufacture provided by the invention. Dosage form 10, in drawing FIG. 3, comprises an external coat on a the exterior surface of dosage form 10. Coat 26 is a therapeutic composition comprising 10 mg to 150 mg of drug 16, represented by dots 16. Exterior coat 26 provides instant drug 16 for instant therapy. Drug 16 is blended with an aqueous-soluble composition comprising a carrier methylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, and blends of hydroxypropylcellulose and hydroxypropylmethylcellulose. Coat 26 optionally comprises polyethylene glycol or acetylated triglycerides. Coat 26 provides instant therapy as coat 26 dissolves or undergoes dissolution in the presence of a biological fluid and concurrently therewith delivers drug 16 to a drug receiving patient. Coat 26 provides instant therapy and it essentially overcomes the time required for the drug to be delivered from the dosage form.

Dosage form 10, as provided by this invention, and as seen in the above drawing figures can be manufactured for administering drug 16 by the oral route, and in another embodiment, dosage form 10 comprising exterior and interior drug 16 can be sized and shaped for administering drug 16 by the sublingual and buccal routes. The sublingual and buccal routes can be used for quicker therapy and they can be used when a smaller dose of drug 16 is needed for therapy. The buccal and sublingual routes can be used as a by-pass of the first pass of hepatic metabolism of drug 16. The sublingual or buccal routes can be used for administering the first dose of drug, followed by permitting dosage form 10 to enter the gastrointestinal tract for subsequent drug delivery.

Dosage form 10, when manufactured as an osmotic, controlled-release dosage form, comprises at least one passageway 13, or more than one passageway 13. The expression "at least one passageway" includes aperture, orifice, bore, pore, porous element through which the drug can be pumped, diffuse, travel or migrate, hollow fiber, capillary tube, porous overlay, porous insert, microporous member, porous composition, and the like. The expression also includes a material that erodes or is leached from wall 12 in the fluid environment of use to produce at least one passageway in dosage form 10. Representative material suitable for forming at least one passageway, or a multiplicity of passageways, includes an erodible poly(glycolic) acid or poly(lactic) acid member in the wall; a gelatinous filament; poly(vinyl alcohol); leachable materials such as fluid removable pore forming polysaccharides, salts, or oxides, and the like. A passageway or a plurality of passageways can be formed by leaching a material such as sorbitol, sucrose,

lactose, fructose, or the like, from the wall to provide an osmotic dimensioned pore-passageway. The passageway can have any shape such as round, triangular, square, elliptical, and the like, for assisting in the metered release of drug from dosage form 10. Dosage form 10 can be constructed with one or passageways in spaced apart relation on one or more than a single surface of a dosage form. Passageways and equipment for forming passages are disclosed in U.S. Pat. Nos. 3,845,770 and 3,916,899 by Theeuwes and Higuchi; in U.S. Pat No. 4,063,064 by Saunders et al; and in U.S. Pat. No. 4,088,864 by Theeuwes et al. Osmotic passageways comprising controlled-drug releasing dimension, sized, shaped and adapted as a drug releasing pore formed by aqueous leaching to provide a drug-releasing pore of controlled osmotic release rate are disclosed in U.S. Pat. No. 4,200,098 by Ayer and Theeuwes; and in U.S. Pat. No. 4,285,987 by Ayer and Theeuwes.

Wall 12 of osmotic dosage form 10 can be formed in one technique using the air suspension procedure. This procedure consists in suspending and tumbling the compressed drug-push core laminate in a current of air and wall forming composition until a wall is applied to the drug-push compartment. The air suspension procedure is well-suited for independently forming the wall. The air suspension procedure is described in U.S. Pat. No. 2,799,241; *J. Am. Pharm. Assoc.*, Volume 48, pages 451 to 454, (1959); and ibid, Volume 49, pages 82 to 84, (196). Osmotic dosage forms can also be coated with a wall forming composition in a Wurster® air suspension coater, using methylene dichloride-methanol cosolvent, 80:20, wt:wt, an ethanol-water, or acetone-water cosolvent, 95:5 wt:wt using 2.5 to 4% solids. The Aeromatic® air suspension coater using a methylene dichloride-methanol cosolvent, 80:20 wt:wt, also can be used for applying the wall. Other wall forming techniques such as pan coating system, where wall forming compositions are deposited by successive spraying of the composition on the drug-push compartment, accompanied by tumbling in a rotating pan. Finally, the wall coated compartments are dried in a forced air over at 30° C. to 50° C. for up to a week to free dosage form 10 of solvent. Generally, the walls formed by these techniques have a thickness of 2 to 30 mils with a presently preferred thickness of 4 to 10 mils.

Dosage form 10 of the invention is manufactured by standard manufacturing techniques. For example, in one manufacture the beneficial drug and other ingredients comprising the drug layer facing the exit means are blended and pressed into a solid layer. The drug and other ingredients can be blended with a solvent and mixed into a solid or semisolid formed by conventional methods such a ball-milling, calendering, stirring or rollmilling and then pressed into a preselected shape. The layer possesses dimensions that correspond to the internal dimensions of the area the layer is to occupy in the dosage form and it also possesses dimensions corresponding to the second layer for forming a contacting arrangement therewith. Next, the push layer, is placed in contact with the drug layer. The push layer is manufactured using techniques for providing the drug layer. The layering of the drug layer and the push layer can be fabricated by conventional press-layering techniques. Finally, the two layer compartment forming members are surrounded and coated with an outer wall. A passageway is laser, leached, or mechanically drilled through the wall to contact the drug layer, with the dosage form optically oricated automatically by the laser equipment for forming the passageway on the preselected surface when a laser is used for forming the passageway.

In another manufacture, the dosage form is manufactured by the wet granulation technique. In the wet granulation technique, for example, the drug and the ingredients comprising the drug layer are blended using an organic solvent, such as isopropyl alcohol-ethylene dichloride 80:20 v:v (volume:volume) as the granulation fluid. Other granulating fluid such as denatured alcohol 100% can be used for this purpose. The ingredients forming the drug layer are individually passed through a 40 mesh screen and then thoroughly blended in a mixer. Next, other ingredients comprising the drug layer are dissolved in a portion of the granulation fluid, such as the cosolvent described above. Then the latter prepared wet blend is slowly added to the drug blend with continual mixing in the blender. The granulating fluid is added until a wet blend is produced, which wet mass then is forced through a 20 mesh screen onto oven trays. The blend is dried for 18 to 24 hours at 30° C. to 50° C. The dry granules are sized then with a 20 mesh screen. Next, a lubricant is passed through an 80 mesh screen and added to the dry screen granule blend. The granulation is put into milling jars and mixed on a jar mill for 1 to 15 minutes. The push layer is made by the same wet granulation techniques. The compositions are pressed into their individual layers in a Manesty® press-layer press.

Another manufacturing process that can be used for providing the compartment-forming composition layers comprises blending the powered ingredients for each layer independently in a fluid bed granulator. After the powered ingredients are dry blended in the granulator, a granulating fluid, for example, poly(vinyl-pyrrolidone) in water, or in denatured alcohol, or in 95:5 ethyl alcohol/water, or in blends of ethanol and water is sprayed onto the powders. Optionally, the ingredients can be dissolved or suspended in the granulating fluid. The coated powders are then dried in a granulator. This process granulates all the ingredients present therein while adding the granulating fluid. After the granules are dried, a lubricant such as stearic acid or magnesium stearate is added to the granulator. The granules for each separate layer are pressed then in the manner described above.

The dosage form of the invention is manufactured in another manufacture by mixing a drug with composition forming ingredients and pressing the composition into a solid lamina possessing dimensions that correspond to the internal dimensions of the compartment. In another manufacture the drug and other drug composition-forming ingredients and a solvent are mixed into a solid, or a semisolid, by conventional methods such as ballmilling, calendering, stirring or rollmilling, and then pressed into a preselected layer forming shape. Next, a layer of a composition comprising an osmopolymer and an optional osmagent are placed in contact with the layer comprising the drug. The layering of the first layer comprising the drug and the second layer comprising the osmopolymer and optional osmagent composition can be accomplished by using a conventional layer press technique. The wall can be applied by molding, spraying or dipping the pressed bilayer's shapes into wall forming materials. Another and presently preferred technique that can be used for applying the wall is the air suspension coating procedure. The procedure consists in suspending and tumbling the two layers in current of air until the wall forming composition surrounds the layers. The air suspension procedure is described in U.S. Pat. No. 2,799, 241; *J. Am. Pharm. Assoc.*, Vol. 48 pp 451–454 (1979); and, ibid, Vol. 49, pp 82–84 (1960). Other standard manufacturing procedures are described in *Modern Plastics Encyclopedia*, Vol 46, pp 62–70 (1969); and in *Pharmaceu-*

tical Science, by Remington, 14th Ed., pp 1626–1678 (1970), published by Mack Publishing Co., Easton, Pa.

Exemplary solvents suitable for manufacturing the wall, the laminates and laminae include inert inorganic and organic solvents final laminated wall. The solvents broadly include members selected for the group consisting of aqueous solvents, alcohols, ketones, esters, ethers, aliphatic hydrocarbons, halogenated solvents, cycloaliphatics, aromatics, heterocyclic solvents and mixtures thereof. Typical solvents include acetone, diacetone, alcohol, methanol, ethanol, isopropyl alcohol, butyl alcohol, methyl acetate, ethyl acetate, isopropyl acetate, n-butyl acetate, methyl isobutyl ketone, methyl propyl ketone, n-hexane, n-heptaene ethylene glycol monoethyl ether, ethylene glycol monoethyl acetate, methylene dichloride, ethylene dichloride, propylene dichloride, carbon tetrachloride, chloroform, nitroethane, nitropropane, tetrachloroethan, ethyl ether, isopropyl ether, cyclohexane, cyclooctane, benzene, toluene, naphtha, tetrahydrofuran, diglyme, aqueous and nonaqueous mixtures thereof, such as acetone and water, acetone and methanol, acetone and ethyl alcohol, methylene dichloride and methanol, and ethylene dichloride and methanol.

DETAILED DISCLOSURE OF EXAMPLES OF THE INVENTION

The following examples are merely illustrative of the present invention and they should not be considered as limiting the scope of the invention in any way as these examples and other equivalents thereof will become apparent to those versed in the art in the light of the present disclosure, the drawings and accompanying claims.

Example 1

A dosage form adapted for delivering a drug in a therapeutic range is manufactured as follows: first a displacement or push layer is prepared by blending and passing through a stainless steel sizing screen having a mesh opening of 420 microns 587.5 grams of sodium carboxymethylcellulose having a degree of polymerization of approximately 3,200 and a degree of substitution of 0.7 carboxymethyl groups per anhydroglucose unit, 300 grams of powdered sodium chloride, 50 grams of hydroxypropylcellulose having a molecular weight of approximately 60,000 grams per mole, and 50 grams of hydroxypropylmethylcellulose having an average methoxyl content of 29 weight percent and an average hydroxypropyl content of 10 weight percent and an average molecular weight of approximately 11,300 grams per mole. Next 10 grams of red ferric oxide were passed through a sizing screen having openings of approximately 250 microns. The resulting powders were mixed in a planetary mixer to a uniform blend. The resulting blend was wet granulated by adding with stirring anhydrous ethyl alcohol until, a cohesive mass was formed. This mass was passed through a sizing screen having openings of approximately 840 microns, forming coated displacement particles, which were an dried overnight at ambient temperature and humidity. The dried particles were then passed again through the 840 micron sizing screen. Next 2.5 grams of magnesium stearate, which had been previously sized through a mesh having 180 micron openings, were tumble mixed into the coated particles.

A composition comprising a drug of the structural formula was prepared as follows: first, a drug composition was prepared by passing 840 grams of venlafaxine hydrochloride, 100 grams of hydroxypropylcellulose having a molecular weight of approximately 60,000 grams per mole, and 50 grams of polyvinylpyrrolidone having a molecular weight of approximately 40,000 grams per mole, were passed through a sizing having openings of approximately 420 microns, and mixed in a planetary mixer to yield a uniform blend. Then, anhydrous ethyl alcohol was added to the mixture with stirring to produce a cohesive damp mass. The resulting damp mass was sized through a sieve having an opening of 840 microns, producing coated venlafaxine drug, which was air dried overnight. The resulting dried coated venlafaxine drug was passed again through the sizing screen having an 840 micron opening. Next, 10 grams of magnesium stearate, sized to 180 microns, was tumble mixed into the blend.

Next, the displacement-push composition and the drug composition were formed into a bilayer core as follows: first, 87 mg of the drug composition was placed in a 9/32 inch round die cavity and lightly tamped with a standard concave round tooling to form a slightly cohesive layer. Then, 70 mg of push composition was added to die and the and the resulting fill was compressed with a final force of 2 tons, thereby forming a two layer cores.

The bilayer cores were placed next in a coating pan having a 12 inch diameter and they were coated with a wall-forming solution. The wall-forming solution was prepared by dissolving 380 grams of cellulose acetate having an acetyl content of 39.8 weight percent in 7,220 grams of acetone. In a separate mixing vessel, 20 grams of polyethylene glycol having a molecular weight of approximately 3,350 grams per mole were dissolved in approximately 380 grams of purified water. The two solutions were mixed to form the wall-coating solution which was spray coated onto the cores until about 20 mg of wall composition was deposited on the surfaces of the bilayer core.

A delivery exit port was formed across the wall by drilling an exit port, centered on the face of the dosage form on the drug composition side of the dosage form. The resulting dosage form was placed in simulated physiological fluid at 37° C., and the dosage form delivered a dose of 73 mg of venlafaxine hydrochloride at a controlled, zero rate over an extended duration of 15 hours.

Example 2

The procedure of Example 1 was followed with the manufacturing procedures as set forth, except that the drug composition comprises 890 grams of venlafaxine hydrochloride, 100 grams of hydroxypropylcellulose, and 10 grams of magnesium stearate. The resulting dosage form released in simulated intestinal fluid 77 mg of venlafaxine hydrochloride at a zero-order rate over an extended duration of 16 hours.

Example 3

The procedure of Example 1 was followed with all manufacturing steps as described, except that the drug composition consists of 650.0 grams of venlafaxine hydrochloride, 240.0 grams of maltodextrin having an average molecular weight of approximately 1800 grams per mole and an average degree of polymerization of 11.1, 80.0 grams of hydroxypropyl cellulose, 20.0 grams of polyvinyl pyrrolidone, and 10.0 grams of magnesium stearate. The resulting dosage form was tested in artificial intestinal fluid, the dosage form delivered a dose of 57 mg of venlafaxine hydrochloride at zero order rate over a period of 15 hours.

Example 4

The procedure of Example 1 was repeated with the manufacture as previously set-forth, except that the drug

composition consists of 840.0 grams of venlafaxine hydrochloride, 150.0 grams of polyethylene oxide having an average molecular weight of approximately 100,000 grams per mole, and 10.0 grams of magnesium stearate. The wall weight weighed approximately 25 mg. The resulting dosage forms were tested in simulated intestinal fluid, and they released a dose of 73 mg of venlafaxine hydrochloride at controlled rate over an extended period of 20 hours.

Example 5

The compositions were manufactured as in Example 1. The process of manufacture was the same except that the push layer manufactured was prepared in a fluid bed aqueous-based granulation process. This was accomplished by sizing the sodium carboxymethyl cellulose, the sodium chloride, the hydroxypropyl cellulose, and red ferric oxide through a screen having openings of 420 microns. The resulting powders were charged into a fluid bed granulation column and binder solution consisting of the hydroxypropyl methylcellulose at a 5 percent solids concentration in water was sprayed on, thereby forming the granules for the push layer.

Example 6

The compositions and processes followed in this example were the same as in Example 1 except the push consisted of 740.0 grams polyethylene oxide with an average molecular weight of approximately 5 million grams per mole, 200.0 grams of sodium chloride, 50.0 grams of hydroxypropyl methyl cellulose having average molecular weight of approximately 11,300 per mole, 5.0 grams of red ferric oxide, and 5.0 grams of magnesium stearate.

DESCRIPTION OF METHOD OF PERFORMING THE INVENTION

Additional embodiments of the invention pertains to a method for delivering a drug embraced by the structural formula of this invention for its intended therapy. One embodiment pertains to a method for delivering a drug of the formula by administering a dosage form comprising 0.5 mg to 750 mg of the drug from a dosage form selected from sustained-release and controlled-release dosage forms in a therapeutically responsive dose over an extended period of time. Another embodiment of the invention pertains to a method for delivering a drug of the formula disclosed in this invention, to the gastrointestinal tract of a human in need of this therapy, wherein the method comprises the steps of: (A) admitting orally into the gastrointestinal tract of the human

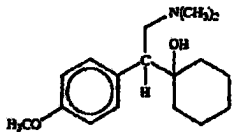
a dosage form comprising: (1) a non-toxic wall composition comprising means for imbibing an external aqueous fluid through the wall into the dosage form, which wall surrounds and defines; (2) an internal compartment; (3) a drug composition comprising a drug of the formula in the compartment comprising a dosage unit amount of said drug; (4) a push composition in the compartment for pushing the drug composition from the compartment; (5) at least one exit means in the wall for delivering the drug from the dosage form; (B) imbibing fluid through the wall into the compartment thereby causing the composition to form a deliverable dosage form and concomitantly causing the push composition to expand and push the drug composition through the exit means from the dosage form; and (C) deliver the therapeutic drug in a therapeutically effective amount at a controlled rate over an extended period of time to the patient in need of said therapy. The method also comprising dispensing a dose amount of said drug from an instant release exterior dosage amount of drug to the patient for providing instant anti-depressant therapy.

Inasmuch as the foregoing specification comprises preferred embodiments of the invention, it is understood that variations and modifications may be made herein, in accordance with the inventive principles disclosed, without departing from the scope of the invention.

We claim:

1. A method for administering a drug to the gastrointestinal tract of a human, wherein the method comprises:

(a) admitting orally into the human a dosage form comprising a drug of the formula:



which drug possess antidepressant therapy and the dosage form comprises a member selected from the group consisting of a sustained-release dosage form and a controlled-release dosage form; and,

(b) administering the drug from the dosage form over an extended period of time in a therapeutically responsive dose to produce the antidepressant therapy.

* * * * *

EXHIBIT 2

REDACTED

EXHIBIT 3

REDACTED

EXHIBIT 4

4

REDACTED

EXHIBIT 5

Wyeth

NEWS RELEASE

IMMEDIATE RELEASE

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Wyeth Reports Earnings Results for the 2006 Third Quarter and First Nine Months

- **Worldwide Net Revenue for the 2006 Third Quarter and First Nine Months Increased 9% and 8% to $5.1 Billion and $15.1 Billion, Respectively**
- **Pharmaceuticals Net Revenue Increased 10% for the 2006 Third Quarter Led by Enbrel® and Prevnar®**
- **Four Regulatory Submissions for New Products**
- **Dividend to Stockholders Increased 4%**
- **2006 Full Year Pro Forma Diluted Earnings per Share Guidance Raised to $3.12 to $3.18**

Madison, N.J., October 19, 2006 - Wyeth (NYSE: WYE) today reported results for the 2006 third quarter and first nine months ending September 30, 2006. Worldwide net revenue increased 9% to $5.1 billion for the 2006 third quarter and 8% to $15.1 billion for the 2006 first nine months. Excluding the favorable impact of foreign exchange, worldwide net revenue increased 7% for the 2006 third quarter. The impact of foreign exchange on worldwide net revenue was not significant for the 2006 first nine months.

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Wyeth (Continued)

"With our outstanding 2006 third quarter, Wyeth is on its way to achieving annual sales of more than $1 billion for six product franchises," said Robert Essner, Chairman and Chief Executive Officer. "We continue to see strong sales from our broad product portfolio, led by our biotechnology products Enbrel and Prevnar. This performance, combined with cost management efforts, provided the rationale for raising our 2006 pro forma diluted earnings per share guidance."

Wyeth previously announced on October 5 that it was raising its 2006 pro forma diluted earnings per share guidance range to $3.12 to $3.18 – an increase of 13% to 16% over 2005 pro forma diluted earnings per share.

2006 Third Quarter Product Highlights

ENBREL® continued to post strong revenue growth during the 2006 third quarter. Wyeth has exclusive rights to Enbrel outside of the United States and Canada where net revenue was $378 million for the 2006 third quarter and $1.1 billion for the 2006 first nine months, increases of 37% and 38%, respectively, over the comparable periods in 2005. Enbrel sales in the United States and Canada are expected to be reported by Wyeth's marketing partner Amgen Inc. on Monday, October 23.

Enbrel is a breakthrough product approved for the treatment of chronic inflammatory diseases, including rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and psoriasis. Enbrel is 10th among the top pharmaceutical products ranked globally by sales and is the second fastest growing product in the top 10.

Wyeth (Continued)

Enbrel continues to be Wyeth's top-selling product in Europe, where sales were $316 million during the third quarter.

PREVNAR®, Wyeth's vaccine to prevent invasive pneumococcal disease in both infants and young children, achieved net revenue of $510 million for the 2006 third quarter and $1.5 billion for the 2006 first nine months, increases of 30% and 32%, respectively, over the comparable periods in 2005. A major contributor to Prevnar's performance in the third quarter was the commencement of national immunization programs in the United Kingdom, Germany and Mexico. Prevnar continues to be the world's best-selling vaccine and now is available in 70 countries worldwide.

Worldwide net revenue for **EFFEXOR®** (Effexor and Effexor XR), the number one selling antidepressant globally and an important therapy in treating adult patients with major depressive disorder, generalized anxiety disorder, social anxiety disorder and panic disorder, was $924 million for the 2006 third quarter and $2.8 billion for the 2006 first nine months, increases of 7% and 6%, respectively, over the comparable periods in 2005. U.S. revenue for Effexor XR, the novel extended release formulation representing more than 90% of overall venlafaxine use, also contributed to growth in the third quarter despite the presence of the older immediate release formulation that became available as a generic under license from Wyeth in August 2006.

PROTONIX®, a proton pump inhibitor indicated for the healing and symptomatic relief of erosive esophagitis (severe heartburn), posted net revenue of $452 million for the 2006 third quarter and $1.4 billion for the 2006 first nine months, increases of 12% and 9%, respectively, over the comparable periods in 2005.

Wyeth (Continued)

2006 Third Quarter Results

Reported net income and diluted earnings per share for the 2006 third quarter were $1,156.9 million and $0.85, respectively, compared with $869.9 million and $0.64 for the 2005 third quarter. Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123R, which requires the expensing of stock options. The 2006 third quarter results included stock option expense, which reduced diluted earnings per share by approximately $0.03. The 2005 third quarter results, which have not been restated to include the impact of expensing stock options, would have been lower by approximately $0.04 per share had stock options been expensed.

The 2006 third quarter results also included charges of $80.2 million ($54.9 million after-tax or $0.04 per share-diluted) related to the Company's productivity initiatives and a favorable income tax adjustment of $70.4 million ($0.05 per share-diluted) related to a reduction of certain deferred tax asset valuation allowances, which are discussed below in greater detail. The 2005 third quarter results included net charges of $95.8 million ($63.4 million after-tax or $0.05 per share-diluted) related to the Company's productivity initiatives and an income tax charge of $170.0 million ($0.12 per share-diluted) recorded in connection with the Company's decision to repatriate approximately $3.1 billion of foreign earnings in accordance with the American Jobs Creation Act of 2004. The 2006 and 2005 productivity initiatives charges, the 2006 favorable income tax adjustment and the 2005 income tax charge are considered to be certain significant items for purposes of analyzing the Company's results of operations. For the 2006 third quarter, net income and diluted earnings per share, before certain significant items, were $1,141.4 million and $0.84, respectively.

Wyeth (Continued)

For the 2005 third quarter, net income and diluted earnings per share, before significant items and assuming stock option expensing, would have been $1,053.1 million and $0.77, respectively.

To assist in performing third quarter comparisons, a pro forma presentation is provided under "Results of Operations – As Adjusted" at the end of this press release.

The increases in net income and diluted earnings per share for the 2006 third quarter, before certain significant items and assuming the expensing of stock options in the 2005 third quarter, resulted from higher net revenue, lower cost of goods sold, and lower selling, general and administrative expenses, both as a percentage of net revenue, lower interest expense, net and higher other income, net offset, in part, by higher research and development spending. Included in other income, net were pre-tax gains from product divestitures amounting to approximately $4.4 million and $37.0 million in the 2006 and 2005 third quarter, respectively.

Income Tax Adjustment

In the 2006 third quarter, the Company recorded a favorable income tax adjustment of $70.4 million ($0.05 per share-diluted) within the Provision for Income Taxes due to a release of a previously established valuation allowance against state deferred tax assets. Deferred tax assets result primarily from the recording of certain accruals and reserves that currently are not deductible for tax purposes and from tax loss carry forwards. Valuation allowances had previously been provided for certain state deferred tax assets due to uncertainty of generating sufficient taxable income in these state jurisdictions as a result of the **Redux®** and **Pondimin®** diet drug litigation. Given the progress made in resolving the diet drug litigation

Wyeth (Continued)

2006 First Nine Months Results

Reported net income and diluted earnings per share for the 2006 first nine months were $3,341.3 million and $2.45, respectively, compared with $2,924.6 million and $2.16 for the 2005 first nine months. The 2006 first nine months results included stock option expense, which reduced diluted earnings per share by approximately $0.10. The 2005 first nine months results, which have not been restated to include the impact of expensing stock options, would have been lower by approximately $0.13 per share had stock options been expensed.

The 2006 first nine months results also included charges of $154.8 million ($106.4 million after-tax or $0.08 per share-diluted) related to the Company's productivity initiatives and a favorable income tax adjustment of $70.4 million ($0.05 per share-diluted) related to a reduction of certain deferred tax asset valuation allowances, as discussed above. The 2005 nine months included net charges of $95.8 million ($63.4 million after-tax or $0.05 per share-diluted) related to the Company's productivity initiatives and an income tax charge of $170.0 million ($0.12 per share-diluted) recorded in connection with the Company's decision to repatriate foreign earnings, as discussed above. The 2006 and 2005 productivity initiatives charges, the 2006 favorable income tax adjustment and the 2005 income tax charge are considered to be certain significant items for purposes of analyzing the Company's results of operations. For the 2006 first nine months, net income and diluted earnings per share, before certain significant items, were $3,377.3 million and $2.48, respectively. For the 2005 first nine months, net income and diluted earnings per share, before certain significant items and assuming stock option expensing, would have been $2,988.9 million and $2.20, respectively.

Wyeth (Continued)

allowances, and the income tax charge, which relates to the repatriation of foreign earnings, have been excluded due to their nature and magnitude. Wyeth's management believes that excluding these items from the Company's results provides a more appropriate view of the Company's operations for the accounting periods presented.

(2) Stock-based compensation expense for the 2006 third quarter and first nine months has been recorded in accordance with SFAS No. 123R, which the Company adopted as of January 1, 2006. In order to present the results for the 2006 and 2005 third quarter and first nine months on a comparable basis, the 2005 third quarter and first nine months results have been adjusted in the above table to reflect the pro forma effect of expensing stock options in 2005.

These measures should not be considered in isolation or as a substitute for the results of operations and diluted earnings per share prepared in accordance with GAAP.

Gains from product divestitures are not considered certain significant items because they constitute an integral part of the Company's analysis of divisional performance. However, they are important to understanding changes in our reported net income. Excluding the certain significant items and the gains from product divestitures described above, as well as assuming stock option expensing for the 2005 third quarter and first nine months, net income and diluted earnings per share were $1,139.0 million and $0.84, respectively, for the 2006 third quarter as compared with $1,028.8 million and $0.76 for the 2005 third quarter and $3,351.3 million and $2.46, respectively, for the 2006 first nine months as compared with $2,871.8 million and $2.12 for the 2005 first nine months.

Wyeth (Continued)

Segment Information

The following table sets forth worldwide net revenue by reportable segment together with the percentage changes from the comparable period in the prior year:

Net Revenue By Reportable Segment	(UNAUDITED) Three Months Ended 9/30/2006 ($ in 000's)	Increase/ (Decrease)	Nine Months Ended 9/30/2006 ($ in 000's)	Increase/ (Decrease)
Pharmaceuticals	$4,260,502	10%	$12,582,265	10%
Consumer Healthcare	663,341	4%	1,815,532	(2)%
Animal Health	211,953	2%	732,679	5%
Consolidated Total	$5,135,796	9%	$15,130,476	8%

Pharmaceuticals

Worldwide Pharmaceuticals net revenue increased 10% for both the 2006 third quarter and the 2006 first nine months due primarily to higher sales of Prevnar, Enbrel, Effexor, Nutritionals, Protonix, the **Premarin®** family of products, **rhBMP-2** and **Tygacil™** offset, in part, by lower sales of **Zoton®**, which is experiencing generic competition. Additionally, alliance revenue increased 11% to $357.3 million for the 2006 third quarter and 21% to $968.8 million for the 2006 first nine months due primarily to higher sales of Enbrel in the United States and Canada. Excluding the favorable impact of foreign exchange, worldwide Pharmaceuticals net revenue increased 8% for the 2006 third quarter. The impact of foreign exchange on worldwide net revenue was not significant for the 2006 first nine months.

Consumer Healthcare

Worldwide Consumer Healthcare net revenue increased 4% for the 2006 third quarter and decreased 2% for the 2006 first nine months. The increase in the 2006 third quarter was due

Wyeth (Continued)

primarily to an increase in sales of **Advil®**, **Dimetapp®** and **Robitussin®**. The decrease in the 2006 first nine months was due primarily to the absence of 2006 sales of Solgar products, which were divested in the 2005 third quarter, lower sales of Robitussin and **Advil Cold & Sinus®** due to the impact of retailer actions and state legislation related to pseudoephedrine-containing products, offset, in part, by an increase in sales of Advil and **Centrum®**. Excluding the favorable impact of foreign exchange, worldwide Consumer Healthcare net revenue increased 3% for the 2006 third quarter and decreased 3% for the 2006 first nine months.

Animal Health

Worldwide Animal Health net revenue increased 2% for the 2006 third quarter and 5% for the 2006 first nine months due to higher sales of livestock products, partially offset by lower sales of equine products. Increases in net revenue also were attributed to higher sales of companion animal products for the 2006 first nine months. Excluding the favorable impact of foreign exchange, worldwide Animal Health net revenue was flat for the 2006 third quarter. The impact of foreign exchange on Animal Health net revenue was not significant for the 2006 first nine months.

2006 Earnings Guidance

On October 5, 2006, the Company raised its 2006 full year pro forma diluted earnings per share guidance to $3.12 to $3.18. This estimate is considered pro forma as it excludes the third quarter favorable income tax adjustment and any restructuring charges from the Company's productivity initiatives. This estimate assumes, among other things, the

Wyeth (Continued)

passage of the R&D tax credit legislation that currently is being debated by the U.S. Congress and that the credit will be made retroactive to January 1, 2006.

Other Matters

On May 9, 2006, we received a Warning Letter from the FDA that raised several specific concerns about manufacturing at our Guayama, Puerto Rico facility. We submitted a timely response to the FDA, and we are working cooperatively with the agency to address the issues raised in the Warning Letter as quickly and effectively as possible. There are no patient safety concerns associated with the issues raised in the Warning Letter. In response to the Warning Letter, we have taken a number of steps to reinforce compliance at the Guayama site, including improving key standard operating procedures, hiring new personnel, undertaking additional training, expanding the senior leadership presence in Puerto Rico and engaging an independent expert consultant to supplement our oversight of good manufacturing practices, and we will be undertaking additional remedial actions. It remains our goal to resolve these issues as quickly as possible but we cannot exclude the possibility that these issues will result in further regulatory action or delays in the approval of new products or release of approved products manufactured at the Guayama facility.

Wyeth (Continued)

Wyeth is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing and marketing of pharmaceuticals, vaccines, biotechnology products and non-prescription medicines that improve the quality of life for people worldwide. The Company's major divisions include Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Fort Dodge Animal Health.

The statements in this press release that are not historical facts, including the entire section under the caption "2006 Earnings Guidance," are forward-looking statements based on current expectations of future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include risks associated with the inherent uncertainty of the timing and success of product research, development and commercialization (including with respect to our pipeline products), drug pricing and payment for our products by government and third-party payers, manufacturing, data generated on the safety and efficacy of our products, economic conditions including interest and currency exchange rate fluctuations, changes in generally accepted accounting principles, the impact of competitive or generic products, trade buying patterns, global business operations, product liability and other types of litigation, the impact of legislation and regulatory compliance (including whether the R&D tax credit legislation will be passed and made retroactive to January 1, 2006), intellectual property rights, strategic relationships with third parties, environmental liabilities, and other risks and uncertainties, including those detailed from time to time in our periodic reports filed with the Securities and Exchange Commission, including our current reports on Form 8-K, quarterly reports on Form 10-Q and annual report on Form 10-K, particularly the discussion under the caption "Item 1A, Risk Factors." We assume no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

The Company will hold a conference call with research analysts at 9 a.m. Eastern Daylight Time today. The purpose of the call is to review the financial results of the Company for the third quarter and first nine months of 2006. Interested investors and others may listen to the call live or on a delayed basis through the Internet webcast, which may be accessed by visiting the Company's Internet Web site at www.wyeth.com and clicking on the "Investor Relations" hyperlink. Also, for recent announcements and additional information including product sales information, please refer to the Company's Internet Web site.

Wyeth (Continued)

Results of Operations

The comparative results of operations are as follows:
(In thousands except per share amounts)

	(UNAUDITED)			
	Three Months Ended		Nine Months Ended	
	9/30/2006	9/30/2005	9/30/2006	9/30/2005
Net Revenue	$5,135,796	$4,716,261	$15,130,476	$14,009,094
Cost of Goods Sold[1]	1,386,254	1,361,040	4,096,931	4,047,587
Selling, General and Administrative Expenses[1]	1,588,947	1,506,654	4,705,940	4,487,247
Research and Development Expenses[1]	762,623	639,998	2,197,966	1,873,659
Interest (Income) Expense, Net	(8,126)	20,205	(122)	67,356
Other Income, Net [1] [2]	(39,488)	(75,746)	(205,539)	(348,374)
Income Before Income Taxes	1,445,586	1,264,110	4,335,300	3,881,619
Provision for Income Taxes [3]	288,668	394,253	994,009	957,017
Net Income[4]	$1,156,918	$869,857	$3,341,291	$2,924,602
Basic Earnings Per Share[5]	$0.86	$0.65	$2.48	$2.18
Average Number of Common Shares Outstanding During Each Period - Basic	1,345,535	1,341,307	1,345,150	1,338,792
Diluted Earnings Per Share[5]	$0.85	$0.64	$2.45	$2.16
Average Number of Common Shares Outstanding During Each Period - Diluted	1,372,798	1,366,765	1,372,341	1,361,932

(1) The 2006 third quarter included charges of $80,150 ($54,910 after-tax or $0.04 per share-diluted) related to activities associated with the Company's productivity initiatives. Charges of $31,317 were included in Cost of Goods Sold, $43,670 in Selling, General and Administrative Expenses, and $5,163 in Research and Development Expenses. The 2006 first nine months included charges of $154,750 ($106,413 after-tax or $0.08 per share-diluted) related to activities associated with the Company's productivity initiatives. Charges of $86,508 were included in Cost of Goods Sold, $54,764 in Selling, General and Administrative Expenses, and $13,478 in Research and Development Expenses.

The 2005 third quarter and first nine months included a net charge of $95,786 ($63,405 after-tax or $0.05 per share-diluted) related to activities associated with the Company's productivity initiatives. Charges of $69,380 were included within Cost of Goods Sold, $61,413 within Selling, General and Administrative Expenses, and $5,200 within Research and Development Expenses, offset, in part, by asset sale gains of $40,207 included within Other Income, Net.

(2) Other income, net included royalty income for the 2006 third quarter and first nine months of $60,630 and $193,864, respectively, compared with $80,267 and $224,491 for the prior year.

Wyeth (Continued)

(3) The 2006 third quarter and first nine months included a favorable income tax adjustment of $70,363 ($0.05 per share-diluted) related to the reduction of certain deferred tax asset valuation allowances. The 2005 third quarter and first nine months included an income tax charge of $170,000 ($0.12 per share-diluted) related to the repatriation of foreign earnings.

(4) Stock-based compensation expense for the 2006 third quarter and first nine months has been recorded in accordance with SFAS No. 123R, which the Company adopted as of January 1, 2006. The 2006 third quarter and first nine months results included net stock-based compensation expense for stock options, restricted stock and performance share awards totaling $63,900 and $212,436, respectively. The 2005 third quarter and first nine months results included net stock-based compensation expense only for restricted stock and performance share awards of $24,525 and $51,215, respectively. Prior to the adoption of SFAS No. 123R, no expense was recorded for stock options.

(5) The average number of common shares outstanding for diluted earnings per share is higher than for basic earnings per share due to the assumed conversion of the Company's outstanding convertible senior debentures, outstanding stock options, deferred contingent common stock awards, restricted stock awards and convertible preferred stock into common stock equivalents using the treasury stock method. For purposes of calculating diluted earnings per share, interest expense, net of capitalized interest and taxes related to the Company's outstanding convertible senior debentures is added back to reported net income, and the additional common shares (assuming conversion) are included in total shares outstanding. Interest expense, net of capitalized interest and taxes was $8,100 and $21,841 for the 2006 third quarter and first nine months, respectively, compared with $5,520 and $13,997 for the comparable periods in 2005.

Results of Operations – As Adjusted

The 2005 third quarter and first nine months results, as reported above, do not include the impact of expensing stock options. In order to assist in performing year-over-year comparisons during 2006, Wyeth has prepared the following presentation of its results of operations for the three months and nine months ended September 30, 2006 and 2005, adjusted where noted below, to exclude certain significant items during the 2006 and 2005 third quarter and first nine months and to reflect the 2005 third quarter and first nine months pro forma effect of expensing stock options.

Wyeth (Continued)

The comparative results of operations – as adjusted are as follows:
(In thousands except per share amounts)

	(UNAUDITED) - AS ADJUSTED			
	Three Months Ended		Nine Months Ended	
	9/30/2006	9/30/2005	9/30/2006	9/30/2005
Net Revenue	$5,135,796	$4,716,261	$15,130,476	$14,009,094
Cost of Goods Sold[1][2]	1,354,937	1,297,833	4,010,423	3,997,043
Selling, General and Administrative Expenses[1][2]	1,545,277	1,486,501	4,651,176	4,559,761
Research and Development Expenses[1][2]	757,460	654,676	2,184,488	1,934,266
Interest (Income) Expense, Net	(8,126)	20,205	(122)	67,356
Other Income, Net[3]	(39,488)	(35,539)	(205,539)	(308,167)
Income Before Income Taxes	1,525,736	1,292,585	4,490,050	3,758,835
Provision for Income Taxes[1][2]	384,271	239,485	1,112,709	769,947
Net Income[1][2]	$1,141,465	$1,053,100	$3,377,341	$2,988,888
Basic Earnings Per Share[4]	$0.85	$0.79	$2.51	$2.23
Average Number of Common Shares Outstanding During Each Period - Basic	1,345,535	1,341,307	1,345,150	1,338,792
Diluted Earnings Per Share[4]	$0.84	$0.77	$2.48	$2.20
Average Number of Common Shares Outstanding During Each Period - Diluted	1,372,798	1,366,765	1,372,341	1,361,932

(1) Charges of $80,150 ($54,910 after-tax or $0.04 per share-diluted) related to activities associated with the Company's productivity initiatives were excluded from the results of operations for the 2006 third quarter. These charges are considered certain significant items and have been excluded above as follows: $31,317 from Cost of Goods Sold, $43,670 from Selling, General and Administrative Expenses, and $5,163 from Research and Development Expenses. Charges of $154,750 ($106,413 after-tax or $0.08 per share-diluted) related to activities associated with the Company's productivity initiatives were excluded from the results of operations for the 2006 first nine months. These charges are considered certain significant items and have been excluded above as follows: $86,508 from Cost of Goods Sold, $54,764 from Selling, General and Administrative Expenses, and $13,478 from Research and Development Expenses.

Charges of $95,786 ($63,405 after-tax or $0.05 per share-diluted) related to activities associated with the Company's productivity initiatives were excluded from the results of operations for the 2005 third quarter and first nine months. These charges are considered certain significant items and have been excluded above as follows: $69,380 from Cost of Goods Sold, $61,413 from Selling, General and Administrative Expenses and $5,200 from Research and Development Expenses offset, in part, by asset sale gains of $40,207 included within Other Income, Net.

A favorable income tax adjustment of $70,363 ($0.05 per share-diluted) related to the reduction of certain deferred tax asset valuation allowances was excluded from the results of operations for the 2006

Wyeth (Continued)

third quarter and first nine months and an income tax charge of $170,000 ($0.12 per share-diluted) related to the repatriation of foreign earnings was excluded from the 2005 third quarter and first nine months. Both are considered certain significant items.

Wyeth calculates net income before certain significant items by excluding the after-tax effect of items considered by management to be unusual from the net income reported under GAAP. Wyeth's management uses this measure to manage and evaluate the Company's performance and believes it is appropriate to disclose this non-GAAP measure to assist investors with analyzing business performance and trends. The productivity initiatives charges, which include costs associated with the Global Business Operations initiative, the costs of closing certain manufacturing facilities, including accelerated depreciation, certain reorganization expenses and the elimination of certain positions at the Company's facilities have been excluded as these charges are not considered to be indicative of continuing operating results. The favorable income tax adjustment, which relates to the reduction of certain deferred tax asset valuation allowances, and the income tax charge, which relates to the repatriation of foreign earnings, have been excluded due to their nature and magnitude. Wyeth's management believes that excluding these items from the Company's results provides a more appropriate view of the Company's operations for the accounting periods presented.

These measures should not be considered in isolation or as a substitute for the results of operations and diluted earnings per share prepared in accordance with GAAP.

(2) The adjusted results of operations for the 2005 third quarter include the pro forma effect of expensing stock options relating to the Company's stock compensation plans of $6,173 in Cost of Goods Sold, $41,260 in Selling, General and Administrative Expenses, and $19,878 in Research and Development Expenses, as well as a related tax benefit of $17,150. The adjusted results of operations for the 2005 first nine months reflect the pro forma effect of expensing stock options relating to the Company's stock compensation plans of $18,836 in Cost of Goods Sold, $133,927 in Selling, General and Administrative Expenses, and $65,807 in Research and Development Expenses, as well as a related tax benefit of $49,452.

(3) Other income, net included royalty income for the 2006 third quarter and first nine months of $60,630 and $193,864, respectively, compared with $80,267 and $224,491 for the comparable periods in 2005.

(4) The average number of common shares outstanding for diluted earnings per share is higher than for basic earnings per share due to the assumed conversion of the Company's outstanding convertible senior debentures, outstanding stock options, deferred contingent common stock awards, restricted stock awards and convertible preferred stock into common stock equivalents using the treasury stock method. For purposes of calculating diluted earnings per share, interest expense, net of capitalized interest and taxes related to the Comp any's outstanding convertible senior debentures is added back to reported net income, and the additional common shares (assuming conversion) are included in total shares outstanding. Interest expense, net of capitalized interest and taxes was $8,100 and $21,841 for the 2006 third quarter and first nine months, respectively, compared with $5,520 and $13,997 for the comparable periods in 2005.

The pro forma presentation of the Company's 2005 quarterly and full year results of operations reflecting the pro forma effect of stock option expensing within the appropriate line of the results of operations and the pro forma effect on earnings per share for the

Wyeth (Continued)

period presented may be accessed on the Company's Internet Web site at www.wyeth.com by clicking on the "Investor Relations" hyperlink.

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EXHIBIT 6

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EXHIBIT 7

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EXHIBIT 8

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EXHIBIT 11

The Prominence of the Delaware Court of Chancery in the State-Federal Joint Venture of Providing Justice

*By William H. Rehnquist**

I am delighted to participate in marking this historic occasion commemorating the Bicentennial of the Delaware Court of Chancery.

Just five years after the drafting of the United States Constitution and three years after Congress passed the 1789 Judiciary Act[1] establishing the Supreme Court and lower federal courts, the second Delaware Constitution established a Court of Chancery. It is a fair question, I suppose, as to why this merits special recognition, aside from our general civic tradition of celebrating events in one-hundred year intervals. Most states on the Atlantic seaboard were creating courts and judicial systems two hundred years ago and it may be that there should be some justification, something special about the court being celebrated, to merit the fine ceremony which we are witnessing tonight.

In the case of the Delaware Court of Chancery, that something special is its two hundred year stewardship of equity jurisprudence. A chancery court traditionally exists to dispense "equity" as opposed to "law," the province of the law courts. This distinction no longer exists in the federal courts or in most state systems—equity and law have been "merged" and judges can exercise both equitable and legal powers. Equity courts first developed in England many centuries ago as an alternative to the rigidity—some might say the rigor mortis—of the law. In the words of Aristotle, "equity is justice that goes beyond the written law."

Equity jurisdiction had existed in Delaware long before 1792, but it had been exercised by the regular law courts. The decision to establish equity in a separate court of chancery was an unusual decision—a decision counter to the trend in other states, where the idea of giving judges the discretion necessary to exercise broad equity powers was successfully opposed. Thomas Jefferson, never a friend to judicial power, opposed equity and favored limiting judges by detailed legislation. He said, "Relieve the judges

*William H. Rehnquist is the Chief Justice of the United States. These remarks were delivered by Chief Justice Rehnquist in Wilmington, Delaware, on September 18, 1992, on the occasion of the Bicentennial Celebration of the Delaware Court of Chancery.

1. 1 Stat. 73 (1789).

from the rigour [sic] of text law, and permit them, with pretorian discretion, to wander into its equity, and the whole system becomes uncertain." Pennsylvanian John Dickinson had similar sentiments, saying of equity, "every verdict is a confused mixture of private passions and public error, and every court assumes the power of legislation."

William Quillen and Michael Hanrahan, in their fine bicentennial history of the Court of Chancery, state that two factors can explain Delaware's contrarian choice. Because equity in Delaware was a creature of colonial statute rather than royal prerogative, the ideological or philosophical opposition to chancery that had developed in other colonies did not occur in Delaware. They also suggest that politics and the respect for the man who became Delaware's first chancellor, William Killen, played an important role in the process. Delaware was a Federalist bastion in 1792 and Killen, someone who would later be called a Jeffersonian Democrat, was the incumbent Chief Justice of Delaware. His party affiliation made him lack a critical qualification for reappointment in the new regime. He was so well respected for his service during the Revolution, however, that the Chancellor's position was apparently created, in part, as a means of "kicking him upstairs" and making way for a federalist chief justice.

Even if the origins of the Court of Chancery were enmeshed in politics, this in no way detracts from this occasion on which we celebrate the bicentennial of this court. Whatever the precise motivation for its creation, Delaware's step in establishing a court of equity was a signal event in the history of the state, and, eventually, in the legal history of our nation.

The nature of judicial power—whether in the form of a sentence imposed on a criminal defendant, an injunction issued by a court of chancery, or a judgment for money damages—can have an immediate and precise effect on individuals. When the executive proposes a law, or when the legislature enacts a law, they lay down general rules that say, in effect, that in the future certain consequences will be visited upon certain persons who do certain things. But the executive and the legislature have no particular individual before them who will be affected by that prospective law.

Fifteen years ago, I was invited to address the Honors Forum of the University of Delaware. My topic then was "The Nature and Exercise of Judicial Power." To illustrate the distinctions between judicial power and other kinds of power, I recounted the oft-told story of the argument between a bishop and a judge as to whom was the more powerful. The judge began the argument by saying he was the more powerful, because he could say to a criminal defendant before him "You shall be hanged." The bishop responded: "Ah, but I can say to a man "You shall be damned." The judge had the last word as he quickly rejoined: "Yes but when I say you shall be hanged, you *are* hanged."

Judges are responsible for the application of the law to real, live litigants—an awesome responsibility. As Chancellor Allen has remarked from his own considerable experience, because no juries exist in equity, a chan-

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a traditional "law judge." Moreover, the
remedies not only entails the exercise of
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and his successful efforts to integrate th
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3. 349 U.S. 249 (1955).
4. 163 U.S. 537 (1896).

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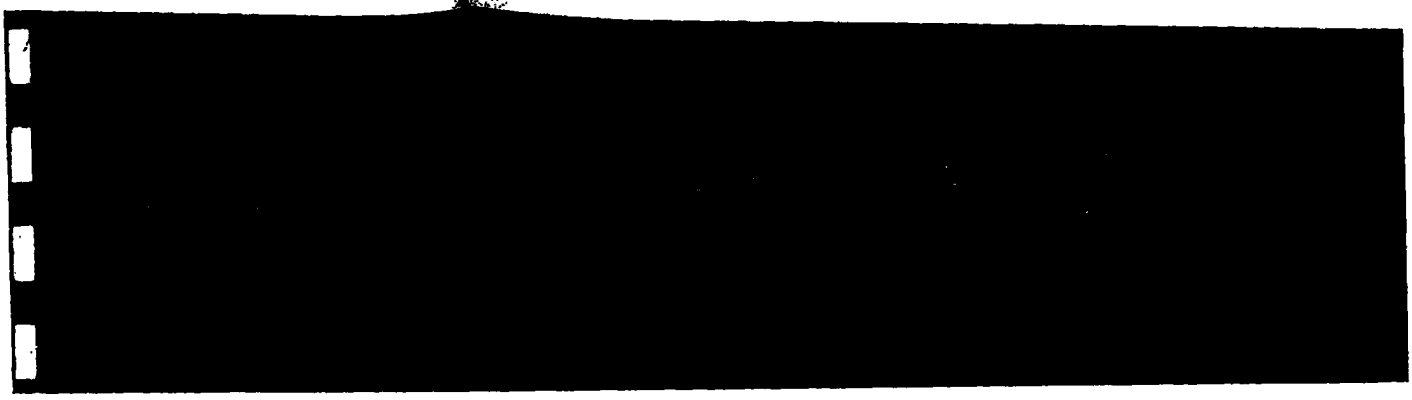
cellor is even more personally responsible for the quality of justice than a traditional "law judge." Moreover, the granting or denial of equitable remedies not only entails the exercise of discretion, but—when redress is granted—the chancellor bears the personal, nondelegable duty to shape an equitable remedy in the fairest and most just manner possible. Finally, in a small state such as Delaware, all judges must achieve what Justice Duffy has called an "accommodation between the detachment required for independent judicial judgment and [an] involvement in community life." This accommodation can create real tension when an unpopular decision is made and the judge is viewed as the responsible party.

In the two hundred years of the Court of Chancery's history, the men who served as Chancellor—and the men and woman who were appointed Vice Chancellors—have discharged their unique responsibility with notable distinction. Indeed, such was the strength of devotion to equitable ideals that we find sons following fathers into the position of Chancellor. Both Kensey Johns, senior and junior, served as Chancellor in the early nineteenth century. Three generations of Wolcotts—James, Josiah and Daniel—also sat as Chancellor. Chancellor Nicholson, whose tenure spanned the turn of this century, was the great-great grandson of the first Chancellor, William Killen.

Among these distinguished Chancellors, several have earned the reputation of "giant." Some have called Chancellor Nicholas Ridgely, who succeeded Chancellor Killen, the "Father of Delaware Equity" for his systematic organization of the substantive and procedural rules of equity and his successful efforts to integrate the Court of Chancery into Delaware's judicial system. Chancellor Curtis and Chancellor Josiah Wolcott presided over the court during the years when major corporate litigation began in earnest, ushering in the era of modern corporate law.

In the eyes of many, Chancellor Collins Seitz' 1952 decision in *Belton v. Gebhart*[2] is the Court of Chancery's "proudest accomplishment." Belton was one of the four cases consolidated in the United States Supreme Court in *Brown v. Board of Education*,[3] and the only one of the four lower court decisions to be affirmed. In *Belton*, Chancellor Seitz courageously held that black schoolchildren suffered from state-imposed segregation. Although he had no power to overrule the separate-but-equal doctrine established by the United States Supreme Court fifty-eight years earlier in *Plessy v. Ferguson*,[4] he nonetheless found that the state was not providing equal facilities. Most importantly, he used the broad equitable powers of the Court of Chancery to order immediate relief. The schoolchildren gained admission to the formerly all-white schools. As you know, after twenty

2. Del. Ch., 87 A.2d 862 (1952), *aff'd*, Del. Supr., 91 A.2d 137 (1952), *aff'd sub. nom.* Brown v. Board of Education, 349 U.S. 294 (1955).
3. 349 U.S. 249 (1955).
4. 163 U.S. 537 (1896).



years on the Court of Chancery, Chancellor Seitz joined the bench of the United States Court of Appeals for the Third Circuit, becoming chief judge and once again distinguishing himself in the performance of his judicial duties.

In light of its 200 year history, the Delaware Court of Chancery deserves our celebration, not only as a unique and vibrant Delaware institution, but as an important contributor to our national system of justice. The Delaware state court system has established its national preeminence in the field of corporation law due in large measure to its Court of Chancery. Because the Court of Chancery, by design, has no jurisdiction over criminal and tort cases—matters which create huge backlogs in other judicial systems—corporate litigation can proceed quickly and effectively. The Delaware Supreme Court, similarly, is poised to act quickly in important corporate cases.

Corporate lawyers across the United States have praised the expertise of the Court of Chancery, noting that since the turn of the century, it has handed down thousands of opinions interpreting virtually every provision of Delaware's corporate law statute. No other state court can make such a claim. As one scholar has observed, "[t]he economies of scale created by the high volume of corporate litigation in Delaware contribute to an efficient and expert court system and bar." Over 50% of the country's major public corporations have chosen to incorporate in Delaware, and the judges of the Court of Chancery and the Delaware Supreme Court are well aware of the national importance their decisions hold.

Perhaps most importantly, practitioners recognize that "[o]utside the takeover process . . . , most Delaware corporations do not find themselves in litigation. The process of decision in the litigated cases has so refined the law that business planners may usually order their affairs to avoid law suits." This recognition confers on the Court of Chancery one of the highest forms of praise the judiciary can receive. As one commentary concluded, "[t]ime is the best test of an institution and, over time, Delaware's law has earned respect and emulation. Such success is not dramatic, but the result of careful, conservative, long time attention." Judicial efficiency and expertise, a well-paid and well-respected judiciary, innovative judicial administration, courageous leadership—these hallmarks of the Delaware Court of Chancery provide a fine example of a somewhat specialized state court system in action.

Today the existence of state courts that do their job promptly and well is more important than ever before. Anyone who has observed trends in the law over the past half-century or so cannot help but be aware of the tendency over this period of time to create more and more claims for relief which can be brought in federal court. The reasons for this trend are many, but one of them is the assertion by those favoring the new federal law that the justice administered by state courts in a particular area in some way falls short. Just as beauty is in the eye of the beholder,

the adequacy of justice is often a matter c
differ. But this argument has prevailed wi

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Constitution, Alexander Hamilton publish
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and emulation. Such success is not dramatic,
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l-paid and well-respected judiciary, innovative
eous leadership—these hallmarks of the Del-
de a fine example of a somewhat specialized

te courts that do their job promptly and well
efore. Anyone who has observed trends in
ury or so cannot help but be aware of the
f time to create more and more claims for
federal court. The reasons for this trend
the assertion by those favoring the new
administered by state courts in a particular
Just as beauty is in the eye of the beholder,

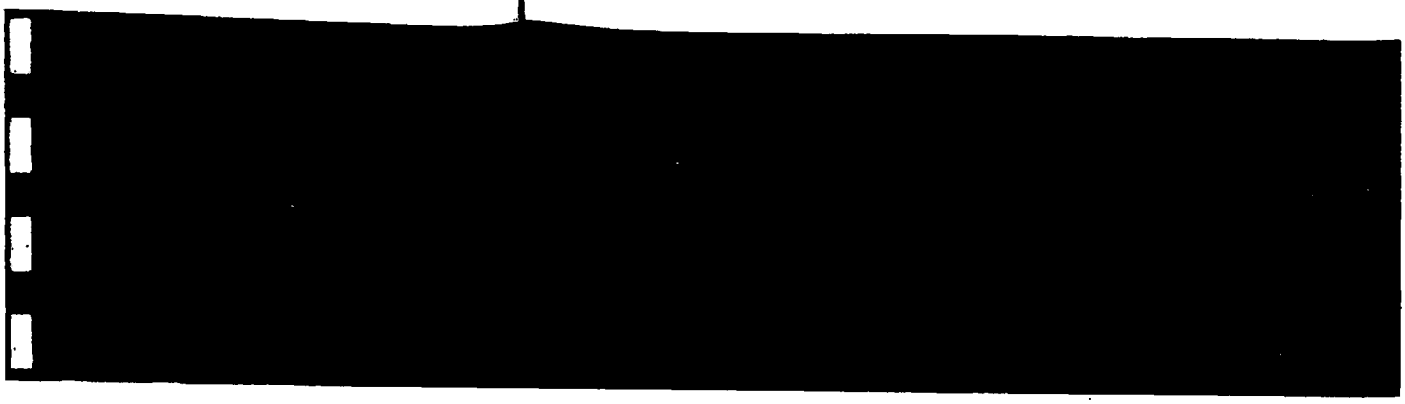
the adequacy of justice is often a matter on which reasonable minds may differ. But this argument has prevailed with Congress time after time.

There are fundamental questions of federalism that lie at the root of this increasing federalization of the law, but this is neither the time nor place to discuss them. So long as the federal judicial system remained relatively specialized and relatively underused, there were some practical advantages to opening the doors of that system to additional suitors. But these advantages have largely disappeared over the past twenty-five years.

The litigation explosion which has taken place over that period of time has profoundly affected federal courts just as it has state courts. The number of federal judgeships has more than doubled in that time, but that increased number of judges work much harder than their predecessors in the often vain hope of simply staying abreast of the vast increase in criminal and civil jurisdiction which Congress has conferred on them.

At the time the states were considering whether to ratify the federal Constitution, Alexander Hamilton published one of the Federalist papers to convince a skeptical audience that the Constitution's mixed judicial system could work. National courts need not overpower or supplant the existing state courts, he argued; instead "the national and state systems are to be regarded as ONE WHOLE." Obviously, Hamilton did not believe that federal and state courts should be consolidated; rather, he understood that the state and federal systems ultimately served the same end—the prompt and fair resolution of disputes. Two hundred years later, we need to reaffirm the view that our state and federal judicial systems are one resource, and an increasingly scarce one at that. The nation can no longer afford the luxury of state and federal systems that work at cross-purposes or irrationally duplicate each other's efforts. Nor can it afford a view that state courts are second-class tribunals in our system of justice.

As we in the judiciary pursue this new—or should I say "renewed"—federalism, the Delaware Court of Chancery provides an excellent example of how state courts are equal partners in the state-federal joint venture of providing justice. On this occasion of the Bicentennial of the Court of Chancery, therefore, I congratulate not only those who have been a part of its proud history—but also those who will continue that tradition in the years ahead. Your unique institution is an inspiration to everyone concerned with the administration of justice in our nation.



CERTIFICATE OF SERVICE

I, Richard L. Renck, hereby certify that on the 16th day of November, 2006, true and correct copies of **OPENING BRIEF IN SUPPORT OF CORDIS CORPORATION'S MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(1) OR, IN THE ALTERNATIVE, TO DISMISS OR STAY THIS ACTION PENDING RESOLUTION OF THE CO-PENDING ACTION IN THE DELAWARE COURT OF CHANCERY** and **Certificate of Service** were served upon the following counsel as noted:

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VIA HAND DELIVERY

/s/ Richard L. Renck (I.D. #3893)

Richard L. Renck (#3893)

CERTIFICATE OF SERVICE

I, Richard L. Renck, hereby certify that on the 21st day of November, 2006, true and correct copies of **REDACTED – PUBLIC VERSION - OPENING BRIEF IN SUPPORT OF CORDIS CORPORATION'S MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(1) OR, IN THE ALTERNATIVE, TO DISMISS OR STAY THIS ACTION PENDING RESOLUTION OF THE CO-PENDING ACTION IN THE DELAWARE COURT OF CHANCERY** and **Certificate of Service** were served upon the following counsel as noted:

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